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, 2024

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 $8.49 of the registrant's common stock as reported on The NASDAQ Global Market on October 31, 2023, the last business day of the registrant's most recently completed second quarter, was approximately $273,160,000.

The number of shares of Registrant's Common Stock outstanding as of June 25, 2024 was 42,735,647.

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 2024. 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, 2024.

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical fact are "forward-looking statements" for purposes of this Annual Report on Form 10-K. These forward-looking statements may include, but are not limited to, statements regarding our 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

We are a clinical stage pharmaceutical company focused on the discovery, development and commercialization of drug therapies for diseases with significant unmet need. We have used our capabilities to develop sebetralstat, a novel, small molecule plasma kallikrein inhibitor targeting the disease hereditary angioedema ("HAE"). In June 2024, we announced that we have filed a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") seeking marketing approval of sebetralstat as the first oral, on-demand therapy for HAE. We also are conducting preclinical development on a novel, oral, Factor XIIa inhibitor program.

HAE is a rare and potentially life-threatening, genetically-driven disease that features episodes of debilitating and often painful swelling in the skin, gastrointestinal tract or airways. Although multiple therapies have been approved for the disease, we believe people living with HAE are in need of alternatives that better meet their objectives for quality of life and ease of disease control. Other than one oral therapy approved for prophylaxis, currently marketed therapies are all administered by injection, which patients find challenging despite their efficacy because they are painful, time consuming to prepare and administer, and difficult to transfer and store. As a result, many attacks are treated too late to prevent significant symptoms, and a large percentage aren't treated at all, leading to needless suffering. We anticipate that there will be strong interest in a safe and effective, orally delivered on-demand treatment, which would provide patients a new and compelling option with which to treat their disease.

Our belief that there could be a fundamental shift in the manner in which HAE is managed is based upon extensive and continuing research we conduct with patients, physicians and payers. We have conducted research to further understand the process that people living with HAE follow when determining what therapy to use, how they treat their attacks and how often they do so. Notably, we have discovered that although people living with HAE understand that treating attacks early will reduce severity and duration, they routinely delay treatment of attacks, often waiting for them to become severe, to avoid the pain and inconvenience of injectable on-demand treatments. Compounding this delay, patients carry their on-demand treatment only one-third of the time when leaving home. We have also learned from many physicians that the challenges associated with injectables often lead to the use of prophylaxis as an alternative, even among patients with a low frequency of attacks.. Patient surveys have indicated to us that if provided with an oral on-demand therapy, most would carry treatment with them all of the time, would treat the vast majority of their attacks, and would treat their attacks far earlier.

In February 2024, we announced positive results from the phase 3 KONFIDENT trial to evaluate the safety and efficacy of sebetralstat as the first potential oral, on-demand therapy for HAE. KONFIDENT was the largest and most representative trial ever conducted in HAE, enrolling a total of 136 patients from 66 clinical sites across 20 countries. Eligible participants included adults and adolescents 12 years of age and older, with or without using long-term prophylaxis, and with all attack severities and locations.

The clinical trial met all primary and key secondary endpoints and demonstrated a safety profile similar to placebo. Based upon these clinical trial results, we submitted a NDA for sebetralstat to the FDA in June 2024. This application seeks approval for sebetralstat as the first oral, on-demand HAE therapy for adults as well as adolescents ages 12 and above with HAE. We believe the adolescent population has a particularly high unmet need, as patients in this age group frequently experience an increase in attacks yet currently only have approved access to intravenously delivered therapies. Market Authorization Application ("MAA") submissions to both the European Medicines Agency ("EMA") and United Kingdom ("U.K.") Medicines and Healthcare products Regulatory Agency ("MHRA") are planned for Q3 2024 and a Japanese New Drug Application ("JNDA") submission to the Japanese Pharmaceuticals and Medical Devices Agency ("JPMDA") is planned for Q4 2024. Regulatory review timelines enable potential launches of sebetralstat in these territories in calendar 2025 and early 2026. To enable the broadest possible global availability of sebetralstat, if approved, we intend to engage commercial partners in other international markets, targeting select initial partners over the course of 2024.

In August 2022, we initiated KONFIDENT-S, a two-year open-label extension trial assessing the long-term safety and tolerability of sebetralstat. In addition, this study is examining the potential use of sebetralstat as short-term prophylaxis in the setting of medical and dental procedures, where HAE attacks are known to be triggered. In total, more than 800 attacks have been treated across KONFIDENT and KONFIDENT-S to date, and KONFIDENT-S includes numerous patients who have taken multiple doses for treatment.

In June 2024 we initiated a pediatric clinical trial (KONFIDENT-KID), using an orally disintegrating tablet ("ODT") formulation of sebetralstat developed specifically for pediatric use. If approved, sebetralstat ODT would be the first oral therapy for pediatric patients aged 2 to 11 years old. In addition, sebetralstat would be only the second FDA-approved on-demand therapy of any type in this population. We also intend to begin conversion of adolescent and adult participants in the ongoing KONFIDENT-S study to an ODT formulation in Q4 2024, enabling a potential 2026 supplemental NDA ("sNDA") approval by the FDA. If approved, the ODT formulation would provide people living with HAE with an additional novel option for oral on-demand treatment.

Sebetralstat has received fast track and orphan drug designations from the FDA, and orphan drug designation in the E.U. A Pediatric Investigational Plan ("PIP") has also been approved by the EMA for sebetralstat. In November 2023, sebetralstat was granted orphan drug status in Switzerland. In February 2024, the U.K. MHRA awarded the Innovation Passport for sebetralstat.

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 recently announced an ongoing review of this program, to evaluate the potential for further progress and indications for future development, and we intend to make further decisions on this program following completion of this process.

Strategy

Key elements of our strategy include:

- *Apply our deep scientific expertise in the area of serine proteases to develop novel oral therapies for indications with high unmet need.* We have assembled a team of chemists and biologists who have demonstrated the ability to design and formulate multiple drug candidate programs from a broad variety of chemical classes, as indicated by our extensive intellectual property portfolio. Our initial focus is specifically on development of oral plasma kallikrein inhibitors for HAE and Factor XIIa inhibitors for other indications; however, we believe our scientific capabilities also can be applied to other proteases to develop therapies for diseases with high unmet need.

- *Grow our capabilities internally as well as through strategic partnerships.* We intend to retain ownership and control of our pipeline programs to key milestones and in certain markets. For certain indications, such as HAE, that can be addressed by a focused organization, we intend to keep all program rights and develop internal sales and marketing capabilities to commercialize the products in major markets. For programs that address larger markets or require greater infrastructure or resources, or for markets outside the U.S. and major E.U. countries, we may seek partners that can provide those capabilities. Decisions on whether, and when, to engage in partnerships or collaborations will be based upon our evaluations of the relative risks and rewards of those collaborations at each point in the development and commercialization cycle.

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.

Hereditary Angioedema

Disease Overview

HAE is a rare and potentially life-threatening genetic condition that occurs in about 1 in 10,000 to 1 in 50,000 people, according to published information from an HAE patient advocacy group. Excessive plasma kallikrein activation 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 patients 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 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. There are currently no therapies specifically approved for normal C1-INH HAE.

Current Treatments and Market Opportunities

There are a number of marketed and development stage therapeutics for HAE, both for prophylaxis as well as on-demand use. Lanadelumab (Takhzyro®) is a monoclonal antibody against plasma kallikrein indicated for prophylaxis to prevent attacks of HAE. The prescribing information recommends subcutaneous administration every two weeks, though dosing at more extended intervals may be considered in some patients. Ecallantide (Kalbitor®) is a small protein inhibitor of plasma kallikrein that is approved for treatment of acute attacks of HAE. While effective, ecallantide has been associated with cases of anaphylaxis and its labeling approval by the FDA includes a boxed warning limiting its administration to healthcare professionals with appropriate medical support to manage anaphylaxis and HAE, and requiring close monitoring of patients. Other therapies provide C1-INH replacement to control plasma kallikrein levels. Marketed C1-INH replacement therapies include Cinryze® and Haegarda® for prophylaxis, and Berinert® for treatment of acute attacks, all of which are purified from human plasma, and Ruconest® which is a recombinant product also for treatment of acute attacks. Icatibant (Firazyr®) is a synthetic peptide-based antagonist that blocks the activity of bradykinin and is indicated for treatment of acute attacks. All of these products are administered by injection, which is typically less convenient for patients and has the potential to reduce compliance. Berotralstat (Orladeyo®) is an oral prophylactic treatment which was launched in 2021. 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 therapy. We believe that a safe and effective oral on-demand agent has the potential to transform treatment for this disease.

We believe a further future market opportunity may exist in treatment of normal C1-INH HAE. Estimates of the size of this patient population vary widely, but we believe that given the significant disease burden of normal C1-INH HAE these patients could benefit from a safe and rapidly effective, oral on-demand plasma kallikrein inhibitor therapy. There are no therapies currently approved specifically for normal C1-INH HAE.

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.

In February 2024, we announced positive results from the phase 3 KONFIDENT trial to evaluate the safety and efficacy of sebetralstat as the first potential oral, on-demand therapy for HAE. KONFIDENT was the largest and most representative trial ever conducted in HAE, enrolling a total of 136 patients from 66 clinical sites across 20 countries. Eligible participants included adults and adolescents 12 years of age or older, with or without using long-term prophylaxis, and with all attack severities and locations.

The clinical trial met all primary and key secondary endpoints and demonstrated a safety profile similar to placebo. Based upon these clinical trial results, we submitted an NDA for sebetralstat to the FDA in June 2024. This application seeks approval for sebetralstat as the first oral, on-demand HAE therapy for adults as well as adolescents ages 12 and above with HAE. MAA submissions to both EMA and MHRA are planned for Q3 2024 and JNDA submission to JPMDA are planned for Q4 2024.

Sebetralstat has received fast track and orphan drug designation from the FDA, and orphan drug designation in the E.U. A PIP has also been approved by the EMA for sebetralstat. In November 2023, sebetralstat was granted orphan drug status in Switzerland. In February 2024, the MHRA awarded the Innovation Passport for sebetralstat.

Competition

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. 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.

Intellectual Property

Our success substantially depends on our ability to obtain and maintain patents and other forms of intellectual property rights for our product candidates, methods used to manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. 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, 2024, we are the owner of, and intend to maintain, eight U.S. patents expiring between 2035 and 2049, absent any extensions, as well as six pending U.S. patent applications and one pending U.S. provisional application. 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, 2024, we are the owner of, and intend to maintain, approximately 102 pending foreign applications and approximately 313 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, 2024, we also are the owner of, and intend to maintain, two pending international applications that, if issued, are expected to expire between 2043 and 2044, 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, 2024, we are the owner of, and intend to maintain, six pending U.S. patent applications, three pending U.S. provisional applications, three pending international applications, and approximately 110 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, 2024, we are the owner of, and intend to maintain, trademark registrations for “KALVISTA” and separately for the K Design in the U.S., twelve 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.). We also own pending trademark applications for “KALVISTA” and the K Design in multiple foreign countries.

We have also applied for registration of potential product names for sebetralstat. As of April 30,2024, we are the owner of, and intend to maintain, trademark registrations for the primary candidate name in the U.S., seven foreign countries as well as all E.U. member states via an E.U. Trade Mark. As of April 30, 2024, we are the owner of trademark registrations for the secondary candidate name in the U.S., eleven foreign countries, as well as all E.U. member states via an E.U. Trade Mark.

We are in the process of obtaining design patent protection in the U.S. and certain countries outside the U.S. for the appearance of some of our products. As of April 30, 2024, we are the owner of, and intend to maintain, one pending U.S. design patent application, and pending design patent applications in 20 foreign countries, as well as all E.U. member states via an International Design Application designating the E.U.

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. 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 marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into 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 to complete the review of NDAs. Most applications are classified as Standard Review products that are reviewed within ten months of the date the FDA files the NDA; most applications classified as Priority Review are reviewed within six months of the date the FDA files the NDA. An NDA can be classified 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 or more additional months to consider certain late-submitted information or information intended to clarify information already provided in the NDA submission.

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 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. 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. For large molecule drugs, sameness is determined based on the principal molecular structural features of a product.

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 post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug 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 application 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. 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 will eliminate, beginning in 2025, the coverage gap under Medicare Part D by significantly lowering the enrollee 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 maximum, and 20% once the out-of-pocket maximum has been reached. Among other things, the IRA also requires HHS to 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 biologics) are eligible to be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. Negotiations for Medicare Part D products began in 2024 with the negotiated price taking effect in 2026, and negotiations for Medicare Part B products begin in 2026 with the negotiated price taking effect in 2028. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations. HHS will announce the negotiated maximum fair prices by September 1, 2024. This price cap, which cannot exceed a statutory ceiling price, will come into effect on January 1, 2026, and will represent a significant discount from average prices to wholesalers and direct purchasers. 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. 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 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. The outcome of these lawsuits is uncertain. 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.

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.

Human Capital Resources

As of April 30, 2024, we had a total of 150 full-time employees, of whom 81 were located in the U.S., 55 were located in the U.K., and 14 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. We emphasize a number of measures and objectives in managing our human capital assets, and we provide our employees with competitive salaries and bonuses, opportunities for equity ownership, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off. In July 2021, the Company adopted an Equity Inducement Plan (the “2021 Equity Inducement Plan”) in order to provide incentives to attract and motivate new employees through the grant of stock options and restricted share units.

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 are a clinical stage company which may make it difficult to evaluate the success of our business to date and to assess our future viability.

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

•If we are unable to successfully develop and commercialize one or more of our compounds, or if we experience significant delays in doing so, the business will be materially harmed.

•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 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.

•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.

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

•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 marketing approval.

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

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

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

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

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

•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.

•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.

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

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

•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. We expect that it could be as much as a year, if ever, before we have a product candidate ready for commercialization. To date, we have financed our operations primarily through sales of our common stock and warrants and a previous option agreement with Merck and associated private placement. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue clinical development of our current product candidates;
- seek to identify additional product candidates;
- acquire or in-license other products and technologies or enter into collaboration arrangements with regards to product discovery;
- initiate clinical trials for additional product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- continue to incur increased costs as a result of operating as a public company.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, obtaining marketing approval for these product candidates and manufacturing, marketing and selling those products for which we may obtain marketing approval. For example, we submitted an NDA to the FDA in June of 2024 for sebetralstat as an on-demand HAE therapy for adults as well as adolescents over age 12 with HAE. We may never succeed in these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our business and could impair our ability to raise capital, maintain our discovery and preclinical development efforts, expand our business or continue our operations and may require us to raise additional capital that may dilute the ownership interest of common stockholders. A decline in the value of our business could also cause stockholders to lose all or part of their investment.

We are a clinical stage company which may make it difficult to evaluate the success of our business to date and to assess our future viability.

We are a clinical stage company and our operations to date have been limited to organizing and staffing, business planning, raising capital, acquiring and developing the technology, identifying potential product candidates, and undertaking up to Phase 3 clinical studies of our most advanced product candidate. We have not yet demonstrated our ability to obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Substantial time is required to develop a new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions made about our future success or viability based on our limited operating history to date may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Upon regulatory approval of our product candidates, we will need to transition from a company with a research focus to a company capable of supporting and scaling commercial activities. We may not be successful in such a transition.

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

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

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings and debt financings. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Risks Related to the Discovery and Development of Our Product Candidates

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

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

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

•execute ongoing clinical development activities;

•move other product candidates into late-stage development;

•obtain required regulatory approvals for the development and commercialization of one or more of our product candidates such as approval by the FDA of the NDA we submitted in June 2024 for the on-demand treatment of HAE attacks in adults and pediatric patients aged 12 years and older;

•maintain, leverage and expand our intellectual property portfolio;

•manufacture a commercial scale product or arrange for a third party to do so on our behalf;

•build and maintain robust sales, distribution and marketing capabilities for successful product commercialization, either on our own or in collaboration with strategic partners;

•gain market acceptance for one or more of our product candidates;

•develop and maintain any strategic relationships we elect to enter into; and

•manage our spending as costs and expenses increase due to drug discovery, preclinical development, clinical trials, regulatory approvals and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop and commercialize sebetralstat or other product candidates, and our business will suffer. Moreover, it is possible that some or all of our product candidates will never obtain marketing authorization even if we expend substantial time and resources seeking such approval.

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

We have not yet commercialized our product candidates and the historical failure rate in clinical drug development of product candidates in our industry is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of its product candidates in humans. Clinical testing is expensive, difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Further, the results of preclinical studies and early clinical trials of 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 marketing approval of their products. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval.

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

•delay or failure in reaching agreement with the FDA, MHRA, EMA 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 clinical research organizations ("CROs") and other third parties;

•clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us to conduct additional clinical trials or abandon product development programs;

•the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;

•we may experience delays or difficulties in the enrollment of patients that our product candidates are designed to target;

•our third party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

•we may have difficulty partnering with experienced CROs that can identify patients that our product candidates are designed to target and run our clinical trials effectively;

•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 marketing approval for our product candidates;

•not obtain marketing approval at all;

•obtain approval for indications or patient populations that are not as broad as intended or desired;

•obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for our products or inhibit our ability to successfully commercialize our products;

•be subject to additional post-marketing restrictions and/or testing requirements; or

•have the product removed from the market after obtaining marketing approval.

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

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to demonstrate safety and efficacy. We 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, IRBs, data safety monitoring boards, or a comparable foreign regulatory authority, or results from earlier stage or concurrent preclinical and clinical studies, that might require modifications to the protocol;

•decisions by the FDA, MHRA, EMA, 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. If we do not meet these milestones as publicly announced, or at all, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

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

If our product candidates are associated with undesirable effects in preclinical or clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Our on-demand HAE program sebetralstat is still in clinical testing. Additional or more severe side effects may be identified for all our programs through further clinical studies. These or other drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may 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 initiated an NDA submission in June 2024 for sebetralstat for the on-demand treatment of HAE attacks in adults and pediatric patients aged 12 years and older. The process of obtaining marketing 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 marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. Securing marketing 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 marketing 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 marketing 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. For example, we submitted an NDA to the FDA in June of 2024 for sebetralstat as an on-demand HAE therapy for adults as well as adolescents over age 12 with HAE, and the FDA must inform us within 60 days of submission if it has not filed our NDA for regulatory review. If the FDA determines that our NDA submission is incomplete or insufficient for filing, the FDA may refuse to file the NDA. Any such refusal by the FDA could require use to expend additional time and resources to revise and resubmit our NDA or harm our business and reputation. Furthermore, there is no guarantee that any revised or resubmitted NDA submission we make will be accepted by the FDA. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application.

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

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

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 or EMA or MHRA 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 a drug 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.

Generally, if a product with an orphan drug designation in a particular jurisdiction subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the 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. and ten years in Europe. Orphan drug exclusivity may be lost if the FDA or EMA 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.

The FDA has granted orphan drug designation for sebetralstat. This designation may not effectively protect sebetralstat (or other drug products for which KalVista seeks orphan designation) from competition because the designation does not preclude different drugs from being approved for the same condition. Even after an orphan 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 marketing approval.

The FDA has granted fast track designation for sebetralstat for the treatment of HAE. We may also seek fast track designation for other indications 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 drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure that the FDA would decide to grant it. Even 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 marketing approval in international jurisdictions would prevent our 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 if the FDA grants marketing approval of a product candidate, in order to market and sell our product candidates in the U.K., E.U. and many other jurisdictions outside of the U.S., we or our third party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain 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 marketing approvals and may not receive necessary approvals to commercialize our products in any market.

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

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA, E.U., MHRA, 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 marketing approvals;

•refusal to permit the import or export of our products;

•product seizure; or

•injunctions or the imposition of civil or criminal penalties.

Non-compliance with U.S., U.K. and E.U. 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 U.K. and E.U.'s requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

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

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

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

In addition, in the United States, 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.

Recently, several healthcare reform initiatives culminated in the enactment of the IRA in August 2022, which, among other things, allows United States Department of Health and Human Services ("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. Negotiations for Medicare Part D products begin in 2024 with the negotiated price taking effect in 2026, and negotiations for Medicare Part B products begin in 2026 with the negotiated price taking effect in 2028. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations. HHS will announce the negotiated maximum fair prices by September 1, 2024. This price cap, which cannot exceed a statutory ceiling price, will come into effect on January 1, 2026, and will 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. In addition, the law eliminates the "donut hole" under Medicare Part D beginning in 2025 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 maximum, and 20% once the out-of-pocket maximum has been reached. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in Patient Protection and Affordable Care Act ("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. The outcome of these lawsuits is uncertain, and some IRA drug discount provisions have not been challenged in litigation. 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 sebetralstat or any future product candidates.

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, though the federal government has not yet approved any such plans. 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 or additional pricing pressures.

We expect that other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

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

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

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

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

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

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

As with all companies, we are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

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.

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 also slow the time necessary for new drugs to be reviewed and/or approved, which would adversely affect our business. 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.

Risks Related to the Commercialization of Our Product Candidates

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

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

- the efficacy and safety and potential advantages and disadvantages compared to alternative treatments;

- the ability to offer our products for sale at competitive prices;

•the convenience and ease of administration compared to alternative treatments;

•the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

•the strength of our marketing and distribution support;

•the availability of third party coverage and adequate reimbursement, including patient cost-sharing programs such as copays and deductibles;

•the ability to develop or partner with third-party collaborators to develop companion diagnostics;

•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.

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

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

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

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

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

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

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the 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, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. Outside the 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. Accordingly, in markets outside the U.S., the reimbursement for our products may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits.

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

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

Our ability to obtain services, reimbursement or funding may be impacted by possible reductions in federal spending in the U.S. as well as globally.

U.S. federal government agencies currently face potentially significant spending reductions. Under the Budget Control Act of 2011, the failure of Congress to enact deficit reduction measures of at least $1.2 trillion for the years 2013 through 2021 triggered automatic cuts to most federal programs. These cuts would include aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2030 unless additional Congressional action is taken.

If government spending is reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve drug research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop. Any reductions in government spending in countries outside the U.S. may also impact us negatively, such as by limiting the functioning of international regulatory agencies in countries outside the U.S. or by eliminating programs on which we may rely.

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

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

•decreased demand for any product candidates or products that we may develop;

•injury to our reputation and significant negative media attention;

•withdrawal of clinical trial participants;

•significant costs to defend the related litigation;

•substantial monetary awards to trial participants or patients;

•loss of revenue;

•reduced resources of our management to pursue our business strategy; and

•the inability to commercialize any products that we may develop.

We currently hold $10 million in product liability insurance coverage in the aggregate, with a per incident limit of $10 million which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Dependence on Third Parties

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

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

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

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

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

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

•reliance on the third party for regulatory compliance and quality assurance;

•the possible breach of the manufacturing agreement by the third party;

•the possible misappropriation of our proprietary information, including trade secrets and know-how; and

•the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third party manufacturers may not be able to comply with cGMP, regulations or similar regulatory requirements outside the 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, the recently proposed BIOSECURE Act introduced in the U.S. House of Representatives, as well as a substantially similar bill in the U.S. Senate, target U.S. government contracts, grants and loans for entities that use equipment and services from certain named Chinese biotechnology companies, and authorizes 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 United States 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 a new third party manufacturers 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 our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We may not successfully engage in strategic transactions, including any additional collaborations we seek, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expenses and present significant distractions to our management. 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 the collaborator terminates the collaboration. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future strategic partners. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner's resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner's evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the 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 our product candidates. If we fail to enter into such collaborations, or such collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.

Biopharmaceutical companies are our prior and likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements. We expect that in any future collaboration agreements, we would have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential development schedule or reduce the scope of research activities, or increase our expenditures and undertake discovery or preclinical development activities at our own expense. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development activities, we may not be able to further develop our product candidates or continue to develop our product candidates and our business may be materially and adversely affected.

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

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities;
- collaborators may delay discovery and preclinical development, provide insufficient funding for product development of targets selected by us, stop or abandon discovery and preclinical development for a product candidate, repeat or conduct new discovery and preclinical development for a product candidate;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than our products;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of its product candidates;
- 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 clinical trial of sebetralstat in pediatric 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 Good Clinical Practice ("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 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. 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 product candidates or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the USPTO to determine priority of invention in the 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 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 our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

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

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

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We seek to protect our confidential proprietary information, in part, by entering into confidentiality and invention or patent assignment agreements with our employees and consultants, however, we cannot be certain that such agreements have been entered into with all relevant parties. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the 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 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 expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

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

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 our product candidates. Our ability to obtain supplies of our 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 research facility in Porton Down, United Kingdom.

Our 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 United States, 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, collaborators and third parties on whom we rely are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Furthermore, we have little or no control over the security measures and computer systems of our third party collaborators. 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 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 the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or 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.

Further, on July 26, 2023, the SEC adopted new 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 new 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 any of our product candidates;
- any adverse changes to our relationship with any manufacturers or suppliers;
- the success of our testing and clinical trials;

•the success of our efforts to acquire or license or discover additional product candidates;

•any intellectual property infringement actions in which we may become involved;

•announcements concerning our competitors or the pharmaceutical industry in general;

•achievement of expected product sales and profitability;

•manufacture, supply or distribution shortages;

•actual or anticipated fluctuations in our operating results;

•FDA or other regulatory actions affecting us or our industry or other healthcare reform measures in the 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, 2024. 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 ("ESG") 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.

Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain regulators, investors, employees, users and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance ("ESG") matters both in the U.S. and internationally. Some investors may use these non-financial performance factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies and actions relating to corporate responsibility are inadequate. We may face reputational damage in the event that we do not meet the ESG standards set by various constituencies.

Further, ESG initiatives, goals or commitments could be difficult to achieve or costly to implement. If our competitors' corporate social responsibility performance is perceived to be better than ours, potential or current investors may elect to invest with our competitors instead. Moreover, California recently adopted two new climate-related bills, which require companies doing business in California that meet certain revenue thresholds to publicly disclose certain greenhouse gas emissions data and climate-related financial risk reports, and compliance with such requirements could require significant effort and resources. Additionally, in March 2024, the SEC enacted comprehensive climate change disclosure rules, although the SEC has since issued an order to stay the rules pending the completion of judicial review of multiple petitions challenging the rules. Our business may face increased scrutiny related to these activities and our related disclosures, including from the investment community, and our failure

to achieve progress or manage the dynamic public sentiment and legal landscape in these areas on a timely basis, or at all, could adversely affect our reputation, business, and financial performance.

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 generated in years after 2017 will only be available to offset up to 80% of our taxable income in any single year (before taking into certain deductions) but will not expire. 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 net operating losses, or NOLs, to offset future taxable income. We have experienced ownership changes in the past that substantially limit 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 in our taxable year ending April 30, 2023 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 excise tax on the repurchase or redemption of stock by certain corporations, beginning in the 2023 tax year. 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. The issuance of additional regulatory or accounting guidance related to the TCJA could materially affect our tax obligations and effective tax rate in the period issued.

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 Director of IT is responsible for implementing and maintaining the information security program. The Director 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 Director of IT reports to our VP of Finance, who together are responsible for coordinating information security risk assessments and overseeing periodic testing of our cybersecurity controls. Our VP of Finance meets with the Audit Committee of our board of directors periodically for the audit committee to provide guidance on the prioritization of the risk remediation and ongoing implementation of cybersecurity improvements across our organization.

The Director 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.

Our corporate headquarters is located in Cambridge, Massachusetts where we occupy approximately 8,300 square feet of office space under a lease agreement that runs through September 2028. We maintain approximately 6,200 square feet of office space in Salt Lake City, Utah under a lease agreement that runs through February 2032. We also maintain approximately 500 square feet of leased research laboratory space in Cambridge, Massachusetts.

Internationally, we maintain approximately 13,400 square feet of office and research laboratory space in Porton Down, United Kingdom, under a lease agreement that runs through April 2028. We also maintain office space in Tokyo, Japan that runs through April 2026 and office space in Zug, Switzerland that runs through October 2024.

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

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not Applicable.

PART II

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

Market Information

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

Holders

As of June 25, 2024, there were 20 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 belief 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 clinical stage pharmaceutical company focused on the discovery, development and commercialization of drug therapies for diseases with significant unmet need. We have used our capabilities to develop sebetralstat, a novel, small molecule plasma kallikrein inhibitor targeting the disease hereditary angioedema ("HAE"). We also are conducting preclinical development on a novel, oral Factor XIIa inhibitor program.

HAE is a rare and potentially life-threatening, genetically-driven disease that features episodes of debilitating and often painful swelling in the skin, gastrointestinal tract or airways. Although multiple therapies have been approved for the disease, we believe people living with HAE are in need of alternatives that better meet their objectives for quality of life and ease of disease control. Other than one oral therapy approved for prophylaxis, currently marketed therapies are all administered by injection, which patients can find challenging despite their efficacy because they can be painful, time consuming to deliver and difficult to store. As a result, many attacks are treated too late to prevent significant symptoms, and a large percentage are not treated at all, which can lead to needless suffering. We anticipate that there will be strong interest in safe and effective, orally delivered, small molecule treatments, and our strategy is to develop oral drug candidates for both on-demand and prophylactic use with the goal of providing patients with a complete set of oral options to treat their disease.

In February 2024 we announced positive results from the phase 3 KONFIDENT trial to evaluate the safety and efficacy of sebetralstat as the first potential oral, on-demand therapy for HAE. KONFIDENT was the largest and most representative trial ever conducted in HAE, enrolling a total of 136 patients from 66 clinical sites across 20 countries. Eligible participants included adults and adolescents 12 years of age and older, with or without using long-term prophylaxis, and with all attack severities and locations.

The clinical trial met all primary and key secondary endpoints and demonstrated a safety profile similar to placebo. Based upon these clinical trial results, we submitted a New Drug Application ("NDA") for sebetralstat to the U.S. Food and Drug Administration ("FDA")in June 2024. We anticipate receiving notification from the FDA on the status of this submission in September 2024. This application seeks approval for sebetralstat as an on-demand HAE therapy for adults as well as adolescents age 12 and above with HAE. We believe the adolescent population has a particularly high unmet need, as patients in this age group frequently experience an increase in attacks yet currently only have approved access to intravenously delivered therapies. Market Authorization Application ("MAA") submissions to both the European Medicines Agency ("EMA") and United Kingdom ("U.K.") Medicines and Healthcare products Regulatory Agency ("MHRA") are planned for Q3 2024 and a Japanese New Drug Application submission to the Japanese Pharmaceuticals and Medical Devices Agency is planned for Q4 2024. Regulatory review timelines enable potential launches of sebetralstat in these territories in calendar 2025 and early 2026. To enable the broadest possible global availability of sebetralstat, if approved, we intend to engage commercial partners in other international markets, targeting select initial partners over the course of 2024.

In August 2022, we initiated KONFIDENT-S, a two-year open-label extension trial assessing the long-term safety and tolerability of sebetralstat. In addition, this study is examining the potential use of sebetralstat as short-term prophylaxis in the setting of medical and dental procedures, where HAE attacks are known to be triggered. In total, more than 800 attacks have been treated across KONFIDENT and KONFIDENT-S to date, and KONFIDENT-S includes numerous patients who have taken multiple doses for treatment.

In June 2024 we initiated a pediatric clinical trial (KONFIDENT-KID) using an orally disintegrating tablet ("ODT") formulation of sebetralstat developed specifically for pediatric use. If approved, sebetralstat ODT would be the first oral therapy for pediatric patients under age 12. In addition, sebetralstat would be only the second FDA-approved on-demand therapy of any type in this population. We also intend to begin conversion of adolescent and adult participants in the ongoing KONFIDENT-S study to an ODT formulation in Q4 2024, enabling a potential 2026 sNDA approval by the FDA. If approved, the ODT formulation would provide people living with HAE with an additional novel option for oral on-demand treatment.

Sebetralstat has received fast track and orphan drug designations from the FDA, 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.

In addition, we are conducting preclinical development of novel, oral Factor XIIa inhibitors, which offer the opportunity for future expansion into other high unmet need indications in therapeutic areas. We recently announced an ongoing review of this program, to evaluate the potential for further progress and indications for future development, and we intend to make further decisions on this program following completion of this process

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

Effective February 14, 2024, we terminated our "at-the-market" program and sales agreement with Cantor Fitzgerald & Co., under which we could, from time to time, offer and sell shares of our common stock having an aggregate offering value of up to $100 million. Prior to delivering the written notice, no shares of our common stock were offered or sold pursuant to this "at-the-market" offering with Cantor Fitzgerald & Co.

On February 14 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 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 net proceeds from the offering, after deducting estimated expenses, were approximately $150.1 million.

We have funded operations primarily through the issuance of capital stock. As of April 30, 2024, we had an accumulated deficit of $469.7 million and hold $210.4 million of cash, cash equivalents and available for sale securities. Our working capital is anticipated to fund our operations for at least the next twelve months from the date the audited consolidated financial statements are issued.

Leadership Transition

In March 2024, we announced the departure of T. Andrew Crockett as Chief Executive Officer and a member of the Board and the promotion of Benjamin L. Palleiko, our then President, Chief Business Officer and Chief Financial Officer, to Chief Executive Officer and his appointment as member of the Board.

Financial Overview

Revenue

We have not generated any revenue in the current fiscal year. To date, we have not generated any revenues from the sale of products, and we do not have any products that have been approved for commercialization. We do not expect to generate product revenue unless and until we obtain regulatory approval for, and commercialize, one of our current or future product candidates.

Research and Development Expenses

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

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

General and Administrative Expenses

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

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

Other Income

Other income consists of bank and investment interest, research and development tax credits from the U.K. government's tax incentive programs set up to encourage research and development in the U.K., realized and unrealized exchange rate gains/losses on cash held in foreign currencies and transactions settled in foreign currencies, and realized gains and losses from sales of marketable securities.

Income Taxes

We historically have incurred net losses and had no corporation tax liabilities. We file U.S. Federal tax returns, as well as certain state returns. We also file tax returns in the U.K. 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.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the 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:

Preclinical and Clinical Trial Accruals

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

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

Results of Operations

This section of this Annual Report on Form 10-K generally discusses fiscal years 2024 and 2023 items and year-to-year comparisons between fiscal years 2024 and 2023. Discussions of fiscal year 2023 items and year-to-year comparisons between fiscal years 2023 and 2022 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, 2023, which was filed with the SEC on July 10, 2023.

Year Ended April 30, 2024 Compared to Year Ended April 30, 2023

The following table sets forth the key components of our results of operations for the years ended April 30, 2024 and 2023:

	Years Ended April 30,		Increase
	2024	2023	(Decrease)
	(in thousands)		
Income			
Revenue	$ —	$ —	$ —
Operating Expenses			
Research and development expenses	86,167	80,276	5,891
General and administrative expenses	54,278	30,595	23,683
Other income			
Interest, exchange rate gain and other income	13,801	17,964	(4,163)

Revenue. No revenue was recognized in the years ended April 30, 2024 or 2023.

Research and Development Expenses. Research and development expenses were $86.2 million in the year ended April 30, 2024 compared to $80.3 million in the prior year. The increase of $5.9 million was primarily due to increases in spending on sebetralstat of $9.5 million, personnel costs of $7.4 million and preclinical and other activities of $0.2 million. These increases were offset by decreases in spending on KVD824 of $11.2 million. The impact of exchange rates on research and development expenses was an increase of approximately $2.6 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, 2024	2023	Increase (Decrease)	
	(in thousands)			
Program-specific costs				
Sebetralstat	$ 36,544	$ 27,037	9,507	35%
KVD824	411	11,651	(11,240)	-96%
Unallocated costs				
Personnel	30,878	23,452	7,426	32%
Preclinical and other activities	18,334	18,136	198	1%
Total	$ 86,167	$ 80,276	$ 5,891	7%

Expenses for the sebetralstat program increased primarily due to the Phase 3 KONFIDENT and KONFIDENT-S trials. We anticipate that these expenses will remain at or slightly below current levels due to the completion of the Phase 3 KONFIDENT trial in February 2024, while the KONFIDENT-S trial continues to enroll participants and we initiate other clinical studies to support the expansion of the sebetralstat commercial opportunity.

Expenses for the KVD824 program decreased primarily due to the termination of the Phase 2 KOMPLETE clinical trial in October 2022. We anticipate that these expenses will cease in the near term as we do not anticipate any further development of KVD824.

Personnel expenses increased primarily due to higher research and development and medical headcount compared to the same period in the prior year. We anticipate that these expenses will continue to increase for the medical team as we support ongoing development activities and prepare for the planned eventual commercialization of sebetralstat.

Expenses for preclinical and other activities increased primarily due to spending in support of HAE awareness within the medical community. We anticipate that these expenses will continue at or above current levels as we continue development on other preclinical activities.

General and Administrative Expenses. General and administrative expenses were $54.3 million in the year ended April 30, 2024 compared to $30.6 million in the prior fiscal year. The increase of $23.7 million was primarily due to increases of $17.2 million in employee-related expenses, $5.0 million in commercial expenses, $0.5 million in professional fees, $0.3 million in travel expenses, $0.2 million in supply chain expenses, $0.2 million in facilities expenses, and $0.3 million in other administrative expenses. We anticipate that expenses will continue at or above current levels as we continue to support the growth of the Company.

Other Income. Other income was $13.8 million for the year ended April 30, 2024 compared to $18.0 million in the prior fiscal year. The decrease of $4.2 million was primarily due to a decrease of $7.3 million in income from research and development tax credit as a result of the tax credit rate change in April 2023. This decrease was offset by an increase of $1.7 million in interest income, an increase in realized gain from available for sale securities of $1.5 million, and foreign currency exchange rate gains of $0.1 million from transactions denominated in foreign currencies in our foreign subsidiaries.

Liquidity and Capital Resources

Since inception, we have not generated any revenue from product sales and have incurred losses since inception and cash outflows from operating activities for the years ended April 30, 2024 and 2023. As of April 30, 2024, we had an accumulated deficit of $469.7 million and cash, cash equivalents and marketable securities totaling $210.4 million. We have not yet commercialized any of our product candidates, which are in various phases of preclinical and clinical development, and we do not expect to generate revenue from sales of any products for the foreseeable future, and will continue to incur net losses as we continue the research and development efforts on our product candidates, hire additional staff, including clinical, scientific, operational, and financial and management personnel.

Sources of Liquidity

On May 21, 2021, we filed a shelf registration statement on Form S-3 pursuant to which the Company may offer and sell securities having an aggregate public offering price of up to $300 million.

In December 2022, we entered into subscription agreements with institutional investors to sell, in a registered direct offering, an aggregate of 9,484,199 shares of our common stock at a price of $6.00 per share and pre-funded warrants to purchase up to 182,470 shares of common stock at a price of $5.999 per pre-funded warrant (the "December 2022 Offering"). The net proceeds from the December 2022 Offering, after deducting estimated expenses, were approximately $57.7 million. In April 2024 all pre-funded warrants from the December 2022 Offering were exercised in a cashless exercise, resulting in an issuance of 182,453 shares of common stock.

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 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 net proceeds from the February 2024 Offering, after deducting estimated expenses, were approximately $150.1 million. As of April 30, 2024 no pre-funded warrants from the February 2024 Offering have been exercised.

Cash Flows

The following table shows a summary of the net cash flow activity for the years ended April 30, 2024 and 2023:

	Years Ended April 30,	
	2024	2023
	(in thousands)	
Cash flows used in operating activities	$ (89,231)	$ (75,261)
Cash flows (used in) provided by investing activities	(84,719)	41,415
Cash flows provided by financing activities	150,714	58,116
Effect of exchange rate changes on cash	(1,213)	1,236
Net (decrease) increase in cash and cash equivalents	$ (24,449)	$ 25,506

Net cash used in operating activities

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. The research and development tax credit receivable decreased due to the tax credit rate change in April 2023. Net cash used in operating activities was $75.3 million for the year ended April 30, 2023 and primarily consisted of a net loss of $92.9 million adjusted for stock-based compensation of $9.9 million, an increase in the research and development tax credit receivable of $2.3 million, and other changes in net working capital.

Net cash (used in) provided by investing activities

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 investing activities was $41.4 million for the year ended April 30, 2023 and consisted of sales and maturities of marketable securities of $140.9 million offset by purchases of marketable securities of $98.3 million and acquisitions of property and equipment of $1.2 million.

Net cash provided by financing activities

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. Net cash provided by financing activities was $58.1 million for the year ended April 30, 2023 and primarily consisted of the $57.7 million in net proceeds from the December 2022 registered direct offering of common stock and pre-funded warrants.

Operating Capital Requirements

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

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

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.

Interest Rate Risk

Because of the short-term nature of the bank deposit arrangements, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations. We do not believe that our cash or cash equivalents have significant risk of default or illiquidity.

We invest in marketable securities in accordance with our investment policy. The primary objectives of our investment policy are to preserve capital, maintain proper liquidity to meet operating needs and maximize yields. We invest our 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 credit exposure. Some of the securities we invest in may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate.

Our investment exposure to market risk for changes in interest rates relates to the increase or decrease in the amount of interest income we can earn on our portfolio, changes in the market value of securities due to changes in interest rates and other market factors. Our investment portfolio includes only marketable securities and instruments with active secondary or resale markets to help ensure portfolio liquidity. An increase or decrease in interest rates along the entire interest rate yield curve would not significantly affect the fair value of our interest sensitive financial instruments, but may affect our future earnings and cash flows. We generally intend to hold our fixed income investments to maturity and therefore do not expect that our operating results, financial position or cash flows will be materially impacted due to a sudden change in interest rates. However, our future investment income may fall short of expectations due to changes in interest rates, or we may suffer losses in principal if forced to sell securities which have declined in market value due to changes in interest rates or other factors, such as changes in credit risk related to the securities' issuers. To minimize this risk, we schedule our investments to have maturities that coincide with our expected cash flow needs, thus avoiding the need to redeem an investment prior to its maturity date. Accordingly, we do not

believe that we have material exposure to interest rate risk arising from our investments. We have not realized any significant losses from our investments.

Foreign Exchange Rate Risk

We maintain cash balances primarily in both U.S. Dollars (“USD”) and British Pound Sterling (“GBP”) to fund ongoing operations and manage foreign exchange risk. Cash, cash equivalents and marketable securities as of April 30, 2024 was composed of $31.8 million in cash and cash equivalents which consisted of readily available checking and bank deposit accounts held primarily in both USD and GBP and $178.6 million of USD denominated marketable securities. As of April 30, 2024, 60% of cash and cash equivalents were held in USD and 39% in GBP. We currently incur significant expense denominated in foreign currencies, primarily in GBP. We do not currently engage in exchange rate hedging or other similar activities to address our exchange rate risk. A 10% change in the exchange rate would result in an immaterial net gain or loss.

During the three months ended April 30, 2024, the Company formed entities in Switzerland and Japan. The Switzerland entity will serve as a subsidiary of the Company’s United Kingdom entity and will use the Swiss Franc ("CHF") as the functional currency for operations. The Japan entity will serve as a subsidiary of the Company’s United States headquarters and will use the Japanese Yen ("JPY") as the functional currency for operations. Both Swiss and Japanese entities do not have any material assets or liabilities as of April 30, 2024, did not generate any revenue, and incurred only de minimis expenses during the three months ended April 30, 2024, as such there in no impact of changes in the foreign currency to USD dollar exchange rate in the financial statements of Company as of and for the three months ended April 30, 2024.

Effects of Inflation

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

Item 8. Financial Statements and Supplementary Data.

The financial statements 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, 2024. 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, 2024 our Chief Executive Officer has concluded that, as of April 30, 2024, 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, 2024. 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, 2024, 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, 2024. 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 quarter ended April 30, 2024 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, 2024, 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

Item 9C. Disclosure Regarding Jurisdictions That Prevent Inspections

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by the Item is set forth in our 2024 Proxy Statement to be filed with the SEC within 120 days of April 30, 2024, and is incorporated by reference into this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required by the Item is set forth in our 2024 Proxy Statement to be filed with the SEC within 120 days of April 30, 2024, 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 Item 403 of Regulation S-K is set forth in our 2024 Proxy Statement to be filed with the SEC within 120 days of April 30, 2024, and is incorporated by reference into this Annual Report on Form 10-K.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of April 30, 2024, with respect to the shares of our common stock that may be issued under our existing equity compensation plans.

Plan Category	(a) Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights		(b) Weighted-average Exercise Price of Outstanding Options, Warrants and Rights (1)	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))	
Equity compensation plans approved by stockholders	4,893,944	(2)	$ 14.89	2,466,455	(3)
Equity compensation plans not approved by stockholders	715,805	(4)	$ 11.26	152,500	(5)
Total	5,609,749			2,618,955	

(1)The weighted average exercise price in column (b) includes options only as performance and restricted stock units do not have an exercise price.

(2)Includes 103,366 shares subject to options issued pursuant to the KalVista Pharmaceuticals Inc. 2015 Incentive Plan, 96,749 shares subject to options issued pursuant to the Enterprise Management Incentives Plan, 3,525,721 shares subject to options issued, 986,272 subject to restricted stock grants, and 181,836 performance stock units issued pursuant to the 2017 Equity Incentive Plan.

(3)As of April 30, 2024, the number of securities remaining available for issuance includes 1,214,875 shares available for future issuance in the form of options under the 2017 Equity Incentive Plan and 1,251,580 shares available for future issuance under the 2017 Employee Stock Purchase Plan

(4)Includes 715,805 shares subject to options issued pursuant to the 2021 Equity Inducement Plan.

(5)As of April 30, 2024, the number of securities remaining available for issuance includes 152,500 shares available for future issuance under the 2021 Equity Inducement Plan.

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

The information required by the Item is set forth in our 2024 Proxy Statement to be filed with the SEC within 120 days of April 30, 2024, and is incorporated by reference into this Annual Report on Form 10-K.

Item 14. Principal Accounting Fees and Services.

The information required by the Item is set forth in our 2024 Proxy Statement to be filed with the SEC within 120 days of April 30, 2024, 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.	10-K	001-36830	10.24	July 16, 2019	
4.3	Form of Pre-Funded Warrant (December 2022 Offering).	8-K	001-36830	4.1	December 27, 2022	
4.4	Form of Pre-Funded Warrant (February 2024 Offering).	10-Q	001-36830	4.1	March 11, 2024	
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#	Amended and Restated Employment Agreement between the Registrant and T. Andrew Crockett, dated June 26, 2019.	10-K	001-36830	10.5	July 16, 2019	
10.6#	Forms of Equity Agreements under the 2017 Equity Incentive Plan.	8-K	001-36830	99.1	June 29, 2018	
10.7	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	
10.8	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	10-Q	001-36830	10.2	March 14, 2019	

	Pharmaceuticals Ltd and Dr. Christopher M. Yea.					
10.13#	Amendment, dated June 26, 2019, to the Service Agreement dated November 1, 2015 by and between KalVista. Pharmaceuticals Ltd and Dr. Christopher M. Yea.	10-K	001-36830	10.23	July 16, 2019	
10.14#	Executive Employment Agreement by and between Registrant and Dr. Paul K. Audhya, MD.	10-K	001-36830	10.18	July 13, 2021	
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	Subscription Agreement, dated as of December 23, 2022, by and among the Registrant and the purchasers identified on the signature page thereto.	8-K	001-36830	10.1	December 27, 2022	
10.17#	Amended and Restated Executive Employment Agreement between the Registrant and Benjamin L. Palleiko, dated March 7, 2024.					X
10.18	Amended and Restated 2021 Equity Inducement Plan and forms of agreement.	S-8	333-280579	99.1	June 28, 2024	
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 Chief Executive Officer (Principal Executive Officer and Financial Officer) pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Chief Executive Officer (Principal Executive Officer and 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					X
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.

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 11, 2024

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 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, Financial and Accounting Officer)	July 11, 2024
/s/ Albert Cha Albert Cha, M.D., Ph.D.	Director	July 11, 2024
/s/ William Fairey William Fairey	Director	July 11, 2024
/s/ Brian J.G. Pereira Brian J.G. Pereira, M.D.	Director and Chairman	July 11, 2024
/s/ Nancy Stuart Nancy Stuart	Director	July 11, 2024
/s/ Patrick Treanor Patrick Treanor	Director	July 11, 2024
/s/ Edward W. Unkart Edward W. Unkart	Director	July 11, 2024

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, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for each of the three years in the period ended April 30, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended April 30, 2024, 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 Matters

Critical audit matters are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
July 11, 2024

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

KALVISTA PHARMACEUTICALS, INC.
Consolidated Balance Sheets
April 30, 2024 and 2023
(in thousands except share and per share amounts)

	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	$ 31,789	$ 56,238
Marketable securities	178,612	93,137
Research and development tax credit receivable	8,439	16,568
Prepaid expenses and other current assets	6,850	6,383
Total current assets	225,690	172,326
Property and equipment, net	2,227	2,948
Right of use assets	6,920	7,822
Other assets	567	106
Total assets	$ 235,404	$ 183,202
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,107	$ 4,817
Accrued expenses	12,398	9,128
Lease liability - current portion	1,302	1,087
Total current liabilities	22,807	15,032
Long-term liabilities:		
Lease liability - net of current portion	6,015	7,145
Total long-term liabilities	6,015	7,145
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value, 100,000,000 authorized		
Shares issued and outstanding: 42,521,975 and 34,171,138 as of April 30, 2024 and 2023, respectively	42	34
Additional paid-in capital	679,754	507,133
Accumulated deficit	(469,726)	(343,082)
Accumulated other comprehensive loss	(3,488)	(3,060)
Total stockholders' equity	206,582	161,025
Total liabilities and stockholders' equity	$ 235,404	$ 183,202

See notes to consolidated financial statements.

KALVISTA PHARMACEUTICALS, INC.
Consolidated Statements of Operations and Comprehensive Loss
Years Ended April 30, 2024, 2023 and 2022
(in thousands, except share and per share amounts)

	2024	2023	2022
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	86,167	80,276	70,167
General and administrative	54,278	30,595	26,446
Total operating expenses	140,445	110,871	96,613
Operating loss	(140,445)	(110,871)	(96,613)
Other income:			
Interest income	3,896	2,232	1,090
Foreign currency exchange gain (loss)	138	90	(1,537)
Other income (expenses), net	9,767	15,642	14,721
Total other income	13,801	17,964	14,274
Loss before income taxes	(126,644)	(92,907)	(82,339)
Income tax (benefit) expense	—	—	—
Net loss	$ (126,644)	$ (92,907)	$ (82,339)
Other comprehensive (loss) income:			
Foreign currency translation loss	(394)	(604)	(1,499)
Unrealized holding gain (loss) on marketable securities	1,291	1,266	(1,511)
Reclassification adjustment for realized (gain) loss on available for sale securities included in net loss	(1,325)	139	581
Total other comprehensive (loss) income:	$ (428)	$ 801	$ (2,429)
Comprehensive loss	$ (127,072)	$ (92,106)	$ (84,768)
Net loss per share, basic and diluted	$ (3.44)	$ (3.33)	$ (3.36)
Weighted average common shares outstanding, basic and diluted	36,786,575	27,890,846	24,473,092

See notes to consolidated financial statements.

KALVISTA PHARMACEUTICALS, INC.
Consolidated Statements of Changes in Stockholders' Equity
Years Ended April 30, 2024, 2023 and 2022
(in thousands, except share and per share amounts)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
Balance at May 1, 2021	24,422,531	$ 24	$ 426,437	$ (167,836)	$ (1,432)	$ 257,193
Issuance of common stock from equity incentive plans	128,217	1	1,581	—	—	1,582
Stock-based compensation expense	—	—	11,086	—	—	11,086
Net loss	—	—	—	(82,339)	—	(82,339)
Foreign currency translation (loss) gain	—	—	—	—	(1,499)	(1,499)
Unrealized holding (loss) gain from marketable securities	—	—	—	—	(1,511)	(1,511)
Reclassification adjustment for realized loss (gain) on marketable securities included in net loss	—	—	—	—	581	581
Balance at April 30, 2022	24,550,748	25	439,104	(250,175)	(3,861)	185,093
Issuance of common stock from equity incentive plans	62,267	—	449	—	—	449
Release of restricted stock units	73,924	—	—	—	—	—
Issuance of common stock, net of issuance costs of $0.3 million	9,484,199	9	56,573	—	—	56,582
Issuance of pre-funded warrants for the purchase of common stock, net of issuance costs	—	—	1,085	—	—	1,085
Stock-based compensation expense	—	—	9,922	—	—	9,922
Net loss	—	—	—	(92,907)	—	(92,907)
Foreign currency translation (loss) gain	—	—	—	—	(604)	(604)
Unrealized holding (loss) gain from marketable securities	—	—	—	—	1,266	1,266
Reclassification adjustment for realized loss (gain) on marketable securities included in net loss	—	—	—	—	139	139
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

See notes to consolidated financial statements.

KALVISTA PHARMACEUTICALS, INC.
Consolidated Statements of Cash Flows
Years Ended April 30, 2024, 2023 and 2022
(in thousands)

	2024	2023	2022
Cash flows from operating activities:			
Net loss	$ (126,644)	$ (92,907)	$ (82,339)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	816	718	564
Stock-based compensation expense	21,915	9,922	11,086
Realized (gain) loss from sale of marketable securities	(1,325)	139	581
Non-cash operating lease expense	(12)	84	179
Amortization of premium on available for sale securities	92	988	2,565
Foreign currency exchange loss (gain)	760	(1,618)	1,552
Changes in operating assets and liabilities:			
Research and development tax credit receivable	8,176	(2,316)	(5,201)
Prepaid expenses and other assets	(538)	6,690	(9,280)
Accounts payable	4,320	1,107	1,687
Accrued expenses	3,209	1,932	472
Net cash used in operating activities	(89,231)	(75,261)	(78,134)
Cash flows from investing activities:			
Purchases of available for sale securities	(189,231)	(98,246)	(136,920)
Sales and maturities of available for sale securities	104,955	140,857	195,711
Acquisition of property and equipment	(42)	(1,196)	(931)
Capitalized website development costs	(401)	—	—
Net cash (used in) provided by investing activities	(84,719)	41,415	57,860
Cash flows from financing activities:			
Issuance of common stock, net of offering expenses	96,945	56,582	—
Issuance of pre-funded warrants	53,123	1,085	—
Issuance of common stock from equity incentive plans	646	449	1,581
Net cash provided by financing activities	150,714	58,116	1,581
Effect of exchange rate changes on cash and cash equivalents	(1,213)	1,236	(1,167)
Net (decrease) increase in cash and cash equivalents	(24,449)	25,506	(19,860)
Cash and cash equivalents, beginning year	56,238	30,732	50,592
Cash and cash equivalents, end of year	$ 31,789	$ 56,238	$ 30,732
Supplemental disclosures of cash flow information:			
Right of use assets obtained in exchange for operating lease liabilities	$ 162	$ 1,192	$ 3,185
Website development costs included in accounts payable	$ 31	$ —	$ —
Property and equipment included in accounts payable and accrued expenses	$ —	$ 47	$ 149

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. (together with its subsidiaries, the "Company") is a clinical stage pharmaceutical company focused on the discovery, development and commercialization of drug therapies for diseases with significant unmet need. The Company's first product candidate is sebetralstat, an inhibitor of plasma kallikrein being developed for hereditary angioedema ("HAE").

In February 2024 the Company disclosed positive phase 3 data from the KONFIDENT trial, testing the safety and efficacy of sebetralstat as a potential oral, on-demand therapy for HAE attacks. The Company submitted a new drug application to the U.S. Food and Drug Administration ("FDA") for sebetralstat in June 2024 and expects to file for approval in the UK, Europe and Japan later in 2024.

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

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

The Company has funded its operations primarily through the issuance of stock. As of April 30, 2024, the Company had an accumulated deficit of $469.7 million and cash, cash equivalents and marketable securities totaling $210.4 million. The Company's working capital, primarily cash, cash equivalents and marketable securities, is anticipated to fund the Company's operations for at least 12 months beyond the date of issuance of the consolidated financial statements.

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

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

Note 2. Summary of Significant Accounting Policies

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

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

Foreign currency: The functional currency of the Company’s United Kingdom (“U.K.”) subsidiary is the British Pound Sterling. Assets and liabilities of the foreign subsidiary are translated using the exchange rate existing on each respective balance sheet date. Revenues and expenses are translated using average exchange rates prevailing throughout the year. The translation adjustments resulting from this process are included as a component of the accumulated other comprehensive loss.

During the three months ended April 30, 2024, the Company formed entities in Switzerland and Japan. The Switzerland entity will serve as a subsidiary of the Company’s United Kingdom entity and will use the Swiss Franc ("CHF") as the functional currency for operations. The Japan entity will serve as a subsidiary of the Company’s United States headquarters and will use the Japanese Yen ("JPY") as the functional currency for operations. If a foreign subsidiary’s functional currency is the local currency, translation adjustments will result from the process of translating the subsidiary’s financial statements into the reporting currency of the Company. Such adjustments are accumulated and reported other comprehensive loss as a separate component of stockholders’ equity.

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.

Recent Accounting Pronouncements: In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach on expected losses to estimate credit losses on certain financial instruments, including trade receivables and available-for-sale debt securities. The new guidance was effective for the Company as of May 1, 2023. The adoption of ASU 2016-13 had no impact on our financial statements and disclosures.

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. ASU No. 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. Early adoption is permitted, and the amendments should be applied retrospectively. The Company does not expect the amendments in this ASU to have a material impact on its consolidated 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.

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

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

Research and development tax credit receivable: The research and development tax credit receivable consists of research and development expenses that have been claimed as research and development tax credits in accordance with the relevant U.K. tax legislation. These refundable tax credits are payable to the Company in cash and are carried on the consolidated balance sheet at the amount claimed and expected to be received from the U.K. government within the next 12 months.

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.

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 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 the incremental common shares issuable upon the exercise of share options and awards.

Potential dilutive common share equivalents consist of:

	April 30,		
	2024	2023	2022
Stock options and awards	5,661,896	5,554,951	3,968,559

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 in 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.

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 similar instruments or for markets that are not active or other inputs that are observable or can be corroborated by observable market data; and Level 3, unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs. These fair values are obtained from independent pricing services, which utilize Level 1 and Level 2 inputs.

The following tables summarize the cash equivalents and marketable securities measured at fair value on a recurring basis as of April 30, 2024 and 2023 (in thousands):

	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

	Level 1	Level 2	Level 3	Balance at April 30, 2023
Cash equivalents	$ 31,507	$ —	$ —	$ 31,507
Marketable securities:				
Corporate debt securities	—	77,967	—	77,967
U.S. government agency securities	—	15,170	—	15,170
	$ 31,507	$ 93,137	$ —	$ 124,644

Note 3. Marketable Securities

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 significant losses from its investments.

The Company classifies all of its investments 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.

Effective May 1, 2023, the Company adopted ASU No. 2016-13 ("ASU 2016-13"), ASC 326, Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments, using the effective date method. As the Company had never recorded any other-than-temporary-impairment adjustments to its available-for-sale debt securities prior to the effective date, no transition provisions were applicable to the Company.

Management evaluated the unrealized losses in available-for-sale ("AFS") debt securities as of April 30, 2024 and 2023 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, 2024 and 2023. 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, 2024 and 2023.

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, 2024 and 2023, respectively, the Company recorded $1.3 million and ($0.1 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, 2024 and 2023 (in thousands):

	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

	April 30, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Corporate debt securities	$ 77,768	$ 367	$ (168)	$ 77,967
Obligations of the U.S. Government and its agencies	15,094	76	—	15,170
Total investments	$ 92,862	$ 443	$ (168)	$ 93,137

The following table summarizes the scheduled maturity for the Company's investments at April 30, 2024 (in thousands):

	April 30, 2024
Maturing in one year or less	$ 80,087
Maturing after one year through two years	84,414
Maturing after two years through four years	14,111
Total investments	$ 178,612

Note 4. Prepaid Expenses and Other Current Assets

At April 30, 2024 and 2023, prepaid expenses and other current assets consisted of (in thousands):

	2024	2023
Prepaid preclinical and clinical activities	$ 1,585	$ 1,724
Other prepaid expenses	2,833	2,583
Interest and other receivables	1,409	654
VAT receivable	1,023	1,422
Total prepaid expenses and other current assets	$ 6,850	$ 6,383

Note 5. Property and Equipment

At April 30, 2024 and 2023, property and equipment consisted of (in thousands):

	2024	2023
Laboratory equipment	$ 2,409	$ 2,404
Office equipment	269	249
Furniture & fixtures	402	398
Leasehold improvements	2,859	2,855
Total property and equipment at cost	5,939	5,906
Less: Accumulated depreciation	(3,712)	(2,958)
Property and equipment, net	$ 2,227	$ 2,948

For the years ended April 30, 2024 and 2023, depreciation expense was $0.8 million and $0.7 million, respectively.

Note 6. Accrued Expenses

At April 30, 2024 and 2023, accrued expenses consisted of (in thousands):

	2024	2023
Accrued research expense	$ 3,416	$ 3,817
Accrued compensation	6,687	4,207
Accrued professional fees	2,042	906
Other accrued expenses	253	198
Total accrued expenses	$ 12,398	$ 9,128

Note 7. Stockholder's Equity

Direct Offerings

On December 23, 2022, the Company entered into subscription agreements with institutional investors to sell, in a registered direct offering, an aggregate of 9,484,199 shares of common stock at a price of $6.00 per share and pre-funded warrants to purchase up to 182,470 shares of common stock at a price of $5.999 per pre-funded warrant (the "December 2022 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 registered direct offering, after deducting $0.3 million in expenses, were approximately $57.7 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. In April 2024 all pre-funded warrants from the December 2022 Offering were exercised in a cashless exercise, resulting in an issuance of 182,453 shares of common stock.

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, 2024, no pre-funded warrants from the February 2024 Offering have been exercised.

Termination of ATM Program

On May 21, 2021, the Company filed a shelf registration statement pursuant to which the Company may offer and sell securities having an aggregate public offering price of up to $300 million. In connection with the filing of the Registration Statement, the Company also entered into a sales agreement with a sales agent, pursuant to which the Company may issue and sell shares of its common stock under an at-the-market (the “ATM”) offering program.

On February 14, 2024, the Company terminated its ATM with Cantor Fitzgerald & Co., under which the Company could, from time to time, offer and sell shares of its common stock having an aggregate offering value of up to $100.0 million. Prior to delivering the written notice, no shares of Company common stock were offered or sold pursuant to this ATM with Cantor Fitzgerald & Co.

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, 2024, 1,214,875 stock awards remain available for grant under the 2017 Equity Incentive Plan (“2017 Plan”). There are 6,977,124 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, 2024 there were 152,500 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. See Note 14, Subsequent Events.

The Company also 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 1,251,580 shares available for future issuance under the ESPP as of April 30, 2024.

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:

	2024	2023	2022
Risk-free interest rate	4.29%	3.11%	1.08%
Expected life of the options	6.25 years	6.25 years	6.25 years
Expected volatility of the underlying stock	81.38%	92.24%	85.4%
Expected dividend rate	0%	0%	0%

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

	Year ended April 30,		
	2024	2023	2022
Research and development	$ 9,305	$ 5,384	$ 5,189
General and administrative	12,610	4,538	5,897
Total stock-based compensation expense	$ 21,915	$ 9,922	$ 11,086

A summary of option activity for the year ended April 30, 2024 is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
Outstanding at May 1, 2023	4,060,175	$ 15.01	6.65	$ 1,668
Options Exercised	(25,182)	7.30		
Options Granted	641,000	10.37		
Options Cancelled	(234,352)	16.60		
Outstanding at April 30, 2024	4,441,641	$ 14.30	5.25	$ 6,505
Exercisable at April 30, 2024	3,366,232	$ 14.89	4.21	$ 5,110
Vested and expected to vest at April 30, 2024	4,441,641	$ 14.30	5.25	$ 6,505

The weighted-average grant date fair value of stock options granted during the years ended April 30, 2024, 2023 and 2022 was $7.57, $7.14, and $16.98, 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, 2024, 2023 and 2022 was $0.1 million, $0.3 million and $0.8 million, respectively. The total cash received by the Company as a result of employee stock option exercises during the years ended April 30, 2024, 2023 and 2022 was $0.2 million, $0.2 million, and $1.4 million, respectively.

As of April 30, 2024, there was $8.8 million of unrecognized compensation expense related to unvested options, which is expected to be recognized over a weighted-average period of 2.3 years.

Restricted Stock Units

During the fiscal year ended April 30, 2024, 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, 2024 is as follows:

	Number of Shares Outstanding	Weighted Average Grant Date Fair Value Per Share
RSU outstanding at April 30, 2023	742,242	7.96
RSUs awarded	250,000	14.38
RSUs released	(341,549)	7.94
RSUs forfeited	(24,421)	8.16
RSUs outstanding at April 30, 2024	626,272	10.52

As of April 30, 2024, the unrecognized stock-based compensation cost related to the RSUs was $6.2 million, which is expected to be recognized over a weighted-average period of 2.96 years

Performance Stock Units

A summary of activity in connection with PSUs for the year ended April 30, 2024 is as follows:

	Number of Shares Outstanding	Weighted Average Grant Date Fair Value Per Share
PSUs outstanding at April 30, 2023	720,000	11.11
PSUs awarded	694,334	11.52
PSUs released	(716,664)	13.18
PSUs forfeited	(155,834)	7.72
PSUs outstanding at April 30, 2024	541,836	9.87

In March 2022, the Company granted 360,000 performance-based restricted stock units (“PSUs”) to five executives under the 2017 Equity Incentive Plan with a grant date fair value of $15.39. The performance-based metric for the awards was the success of the Company’s Phase 3 clinical trial of the sebetralstat program. Upon successful completion of the performance metric, 100% of the PSUs would vest in full. This performance metric was certified by the Compensation Committee of the Company's Board of Directors in February 2024, resulting in $5.5 million of expense recognized in full as of the certification date.

In January 2023, the Company granted 360,000 PSUs to five 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, 2024 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.

In June 2023, the Company granted 306,667 PSUs to seven 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, 2024, $3.0 million of expense from these awards has been recognized.

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 April 30, 2024, $2.2 million of expense from these awards has been recognized.

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, 25% of the PSUs will vest, with the remaining 75% of the PSUs vesting upon successful completion of the NDA approval metric. As of April 30, 2024 the Company has not recognized any compensation expense related to these awards as the achievement of the Performance Metrics are not yet deemed to be probable.

Note 9. Commitments and Contingencies

Clinical Studies: The Company enters into contractual agreements with contract research organizations in connection with preclinical and toxicology studies and clinical trials. Amounts due under these agreements are invoiced to the Company on predetermined schedules during the course of the 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 $23.8 million as of April 30, 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.

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, 2024 and 2023.

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

Note 10. Leases

The Company has a lease agreement for approximately 8,300 square feet of space for its headquarters located in Cambridge, Massachusetts that runs through September 2028.

The Company has lease agreements for approximately 13,400 square feet of office and research laboratory space located in Porton Down, United Kingdom that runs through April 2028.

The Company has a lease agreement in Salt Lake City, Utah for approximately 6,200 square feet of office space that commenced in November 2021 that runs through February 2032.

The Company has a lease agreement for approximately 500 square feet of research laboratory space in Cambridge, Massachusetts that commenced in July 2022 with an option to renew annually.

The Company has a lease agreement for office space in Zug, Switzerland that commenced in August 2023 with an option to renew annually.

The Company has a lease agreement for office space in Tokyo, Japan that commenced in April 2024 and runs through April 2026.

The Company is also party to several operating leases for office and laboratory space as well as certain lab equipment. Total rent expense was $2.0 million, $1.8 million and $1.7 million for the years ended April 30, 2024, 2023 and 2022, respectively and is reflected in general and administrative expenses and research and development expenses as determined by the underlying activities.

Incremental borrowing rate – The Company's lease agreements do not provide an implicit rate. The Company estimated the incremental borrowing rate based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term and economic environment.

Lease and non-lease components – The Company has elected the practical expedient which allows non-lease components to be combined with 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.

The following table summarizes lease costs included in research and development and general and administrative expense for the years ended April 30, 2024 and 2023 (in thousands):

	2024	2023
Operating lease costs	$ 1,813	$ 1,806
Short-term lease costs	114	13
Variable lease costs	238	174
Total lease costs	$ 2,165	$ 1,993

The following table summarizes the undiscounted payments due under lease liabilities and the present value of those liabilities as of April 30, 2024 (in thousands):

Years ending April 30,	Operating Leases
2025	$ 1,867
2026	1,896
2027	1,849
2028	1,870
2029	848
Thereafter	664
Total lease payments	8,994
Less: imputed interest	1,677
Total lease liabilities	7,317
Current lease liabilities	1,302
Long-term lease liabilities	$ 6,015

The following table summarizes the lease term and discount rate as of April 30, 2024 and 2023:

	2024	2023
Weighted-average remaining lease term (years)	5.0	6.0
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, 2024 and 2023 (in thousands):

	2024	2023
Cash paid for amounts included in the measurement of operating lease liabilities	$ 1,683	$ 1,615

Note 11. Income Taxes

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

	2024	2023	2021
Domestic	$ (52,661)	$ (27,437)	$ (21,145)
Foreign	(73,983)	(65,470)	(61,194)
	$ (126,644)	$ (92,907)	$ (82,339)

For the years ended April 30, 2024, 2023 and 2022, 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:

	2024	2023	2021
Income tax benefit at U.S. federal statutory rate	21.0%	21.0%	21.0%
Foreign rate differential	2.3%	2.8%	(1.5)%
Nondeductible expenses - UK R&D credit	(8.3)%	(7.7)%	(10.6)%
162(m) permanent adjustment	(1.9)%	—	—
Other	(0.4)%	(0.3)%	(0.8)%
Valuation allowance	(12.7)%	(15.8)%	(8.1)%
	—	—	—

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

	2024	2023
Deferred tax assets:		
Net operating loss ("NOL") carryforwards	$ 50,179	$ 35,790
Operating lease liabilities	1,406	1,777
174 capitalization	2,168	3,922
Stock compensation	3,708	3,915
Other	2,506	1,634
Subtotal	59,967	47,038
Less: valuation allowance	(58,537)	(45,276)
Deferred tax assets, net of valuation allowance	1,430	1,762
Deferred tax liabilities:		
Operating lease - Right-of-use assets	(1,325)	(1,693)
Other	(105)	(69)
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, 2024 and 2023, respectively. During the years ended April 30, 2024 and 2023 the valuation allowance changed by $13.3 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 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 a public offering in September 2018. The offering in September of 2018 resulted in an ownership change as of February 2019. The Company reevaluated the 382 position of the company as of April 30, 2024 and concluded that no issuances since February of 2019 have resulted in an ownership change, including the February 2024 Offering.

As of April 30, 2024, the Company has NOL carryforwards for U.S. federal income taxes of $6.1 million that expire in 2036 and $49.7 million that can be carried forward indefinitely. The $6.1 million of NOL expiring in 2036 is subject to an annual 382 limitation of $0.3 million. The $49.7 million of NOL that carries forward indefinitely is not currently subject to an annual 382 limitation. The Company also has NOL carryforwards for state income taxes of $31.9 million that begin to expire in 2036 and NOL carryforwards for U.K. income taxes of $145.6 million that do not expire. The company also has a small amount of NOLs in the jurisdictions of Ireland, Switzerland, and Japan that total less than $2.0 million and do not expire.

The Company has $83.0 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 $0.3 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 limit the company to $0.1 million of credits to utilize, with $1.4 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 tax returns in the U.K and Ireland. The Company is subject to U.S. Federal, state, and U.K. income tax examinations by authorities for tax years ending after 2019. There are currently no federal, state, or U.K. audits in process. Tax year 2020 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, 2024 and 2023, respectively.

As part of the Tax Cuts and Jobs Act of 2017 (TCJA), beginning with the Company's 2022 tax year, the Company is required to capitalize research and development expenses, as defined under Internal Revenue Code section 174. For expenses that are incurred for research and development in the U.S., the amounts will be amortized over 5 years, and expenses that are incurred for research and experimentation outside the U.S. will be amortized over 15 years. This provision has not had a significant impact to the consolidated financial statements.

Note 12. Defined Contribution Plans

Participation in a personal pension plan is available to all U.K. based employees of the Company upon commencement of their employment. Employer contributions are made in accordance with the terms and conditions of the employment contract. Employees 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. Total employer contributions to both plans for the years ended April 30, 2024, 2023 and 2022 were $1.1 million, $0.8 million and $0.6 million respectively.

Note 13. Other Income (Expenses), Net

At April 30, 2024 and 2023, other income and expenses consisted of (in thousands):

	2024	2023	2022
R&D tax credit	$ 8,452	$ 15,785	$ 15,303
Realized gain (loss) on sale of securities	1,325	(139)	(581)
Miscellaneous	(10)	(4)	(1)
Other income (expenses), net	$ 9,767	$ 15,642	$ 14,721

As of April 30, 2024 and 2023 the Company had research and development tax credits receivable totaling $8.4 million and $16.6 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 $8.5 million and $15.8 million related to these programs in the years ended April 30, 2024 and 2023, 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.

In November 2022, the U.K. government announced changes to the research and development tax credit program. These changes, which include a reduction in tax credit rates for SMEs, were effective on April 1, 2023 and reduced the payable tax credit of approximately 33.4% for eligible research and development expenditures to 18.6%. Additionally, the cash rebate that subcontracted research expenditures are eligible for decreased from approximately 21.7% to 12.1% after April 1, 2023.

Note 14. Subsequent Events

In June 2024, the Company amended and restated the 2021 Equity Inducement Plan to register 600,000 additional 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 563(c)(4) of the Nasdaq Listing Rules.

Exhibit 10.17#

AMENDED AND RESTATED EXECUTIVE EMPLOYMENT AGREEMENT

This Amended and Restated Executive Employment Agreement ("**Agreement**") is made and entered into on this 7th day of March, 2024 by and between KalVista Pharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Benjamin L. Palleiko (hereinafter, the "**Executive**").

RECITALS

WHEREAS, the Executive is currently employed by the Company;

WHEREAS, the terms of Executive's employment with the Company are set forth in an Amended and Restated Executive Employment Agreement by and between the Company and the Executive previously entered into on the 8th day of June, 2023 (the "**Second Agreement**");

WHEREAS, the Company and the Executive now desire to amend and restate the Second Agreement;

WHEREAS, the Company and Employee intend that this Agreement shall supersede and replace the Second Agreement; and

WHEREAS, the Company desires to continue to employ the Executive and the Executive desires to continue to be employed by the Company on the terms herein described.

NOW, THEREFORE, in consideration of the premises and mutual covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are mutually acknowledged, the Company and the Executive hereby agree as follows:

1.Employment. The Company hereby agrees to employ the Executive and the Executive hereby agrees to serve the Company during the Term of Employment on the terms and conditions set forth herein.

2.Position and Duties of Executive. During the Term of Employment, the Executive shall be employed and serve as the Chief Executive Officer of the Company, and shall have such duties typically associated with such titles, including, without limitation supervising operations and management of the Company and its subsidiaries. The Executive shall faithfully and diligently perform all services as may be assigned to him by the Board, and shall exercise such power and authority as may from time to time be delegated to him by the Board. The Executive shall devote his full business time, attention and efforts to the performance of his duties under this Agreement, render such services to the best of his ability, and use his reasonable best efforts to promote the interests of the Company. The Executive shall not engage in any other business or occupation during the Term of Employment, including, without limitation, any activity that (i) conflicts with the interests of the Company or its subsidiaries, (ii) interferes with the proper and efficient performance of his duties for the Company, or (iii) interferes with the exercise of his judgment in the Company's best interests. Notwithstanding the foregoing or any other provision of this Agreement, it shall not be a breach or violation of this Agreement for the Executive to (w) serve on up to two outside corporate or scientific advisory boards with prior notice to the Company, (x) serve on civic or charitable boards or committees, (y) deliver lectures or fulfill speaking

engagements, or (z) manage personal investments, so long as any such activities do not interfere with or detract from the performance of the Executive's responsibilities to the Company in accordance with this Agreement.

3.Compensation and Benefits.

(a)*Base Salary*. The Executive shall receive a Base Salary at the annual rate of $661,800, effective as of the date hereof, during the Term of Employment, with such Base Salary payable in installments consistent with the Company's normal payroll schedule, subject to applicable withholding and other taxes. The Base Salary shall be reviewed, at least annually, for merit increases and may, by action and in the discretion of the Board (or its Compensation Committee), be increased at any time or from time to time, but may not be decreased from the then current Base Salary.

(b)*Bonuses*. During the Term of Employment, the Executive shall participate in the Company's annual incentive compensation plan, program and/or arrangements applicable to senior-level executives, as established and modified from time to time by the Compensation Committee of the Board in its sole discretion. During the Term of Employment, the Executive shall have a target bonus opportunity under such plan or program equal to 60% of his current Base Salary (the "**Target Bonus**"), based on satisfaction of performance criteria to be established by the Compensation Committee of the Board within the first three months of each fiscal year that begins during the Term of Employment. Payment of annual incentive compensation awards shall be made in the same manner and at the same time that other senior-level executives receive their annual incentive compensation awards, but in no event later than 2 ½ months following the last day of the applicable Company fiscal year, and, except as otherwise provided herein, will be subject to the Executive's continued employment through the last day of the applicable Company fiscal year.

(c)*Compensation/Benefit Programs*. During the Term of Employment, the Executive shall be entitled to participate in all medical, dental, hospitalization, accidental death and dismemberment, disability, travel and life insurance plans, and any and all other plans as are presently and hereinafter offered by the Company to its executive personnel, including savings, pension, profit-sharing and deferred compensation plans, subject to the general eligibility and participation provisions set forth in such plans.

(d)*Equity Awards*. During the Term of Employment, the Executive shall be eligible to be granted Equity Awards. The number and type of such Equity Awards, and the terms and conditions thereof, shall be determined by the Board or the Compensation Committee of the Board, in its discretion

(e)*Vacation*. The Executive shall be entitled to 25 days of paid vacation each calendar year during the Term of Employment, subject to the terms of the Company's then effective vacation or paid time off policy.

(f)*Reimbursement of Reasonable Business Expenses*. Subject to submission of proper substantiation by the Executive, and subject to such rules and guidelines as the Company may from time to time adopt with respect to the reimbursement of reasonable business expenses of executive personnel, the Company shall reimburse the Executive for all reasonable expenses

actually paid or incurred by the Executive during the Term of Employment in the course of and pursuant to the business of the Company. The Executive shall account to the Company in writing for all expenses for which reimbursement is sought and shall supply to the Company copies of all relevant invoices, receipts or other evidence reasonably requested by the Company.

4.Termination.

(a)*General*. The Term of Employment shall terminate upon the earliest to occur of (i) the Executive's death, (ii) a termination by the Company by reason of the Executive's Disability, (iii) a termination by the Company with or without Cause, or (iv) a termination by Executive with or without Good Reason. Upon any termination of Executive's employment for any reason, except as may otherwise be requested by the Company in writing and agreed upon in writing by Executive, the Executive shall resign from any and all directorships, committee memberships or any other positions Executive holds with the Company or any of its Related Entities.

(b)*Termination by the Company for Cause*. The Company shall at all times have the right, upon written notice to the Executive, to terminate the Term of Employment for Cause. In no event shall a termination of the Executive's employment for Cause occur unless the Company gives written notice to the Executive in accordance with this Agreement stating with reasonable specificity the events or actions that constitute Cause. In the event that the Term of Employment is terminated by the Company for Cause, Executive shall be entitled only to the Accrued Obligations.

(c)*Disability*. The Company shall have the option, in accordance with applicable law, to terminate the Term of Employment upon written notice to the Executive at any time during which the Executive is suffering from a Disability. In the event that the Term of Employment is terminated due to the Executive's Disability, the Executive shall be entitled to (i) the Accrued Obligations and (ii) any insurance benefits to which he and his beneficiaries are entitled as a result of his Disability.

(d)*Death*. In the event that the Term of Employment is terminated due to the Executive's death, the Executive's estate shall be entitled to (i) the Accrued Obligations and (ii) any insurance benefits to which he and his beneficiaries are entitled as a result of his death.

(e)Termination Without Cause outside of a Change in Control of the Company or Resignation With Good Reason outside of a Change in Control of the Company. The Company may terminate the Term of Employment without Cause, and the Executive may terminate the Term of Employment for Good Reason, at any time upon written notice. If the Term of Employment is terminated by the Company without Cause (other than due to the Executive's death or Disability) or by the Executive for Good Reason, in either case prior to the date of a Change in Control or more than two years after a Change in Control, the Executive shall be entitled to the following:

(i)The Accrued Obligations;

(ii)A lump sum payment equal to 15 months of Executive's then-current Base Salary;

(iii)Provided that the Executive timely elects continued coverage under COBRA, the Company will reimburse the Executive for the monthly COBRA cost of continued health and dental coverage of the Executive and his qualified beneficiaries paid by the Executive under the health and dental plans of the Company, less the amount that the Executive would be required to contribute for health and dental coverage if the Executive were an active employee of the Company, for 15 months (or, if less, for the duration that such COBRA coverage is available to Executive). Notwithstanding the above, if the Company determines in its sole discretion that it cannot provide the COBRA benefits described herein without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof provide Executive with a taxable lump sum payment in an amount equal to the then-unreimbursed monthly COBRA premiums.

(f)*Termination by Executive Without Good Reason*. The Executive may terminate his employment without Good Reason by providing the Company 30 days' written notice of such termination. In the event of a termination of employment by the Executive under this Section 4(f), the Executive shall be entitled only to the Accrued Obligations. In the event of termination of the Executive's employment under this Section 4(f), the Company may, in its sole and absolute discretion, by written notice, accelerate such date of termination and still have it treated as a termination without Good Reason.

(g) Termination Without Cause in connection with a Change in Control of the Company or Resignation With Good Reason in connection with a Change in Control of the Company. If the Executive's employment is terminated by the Company (or any entity to which the obligations and benefits under this Agreement have been assigned pursuant to Section 9(b)) without Cause or by the Executive for Good Reason, in either case during the two year period immediately following a Change in Control, then the Executive shall be entitled to the following:

(i)The Accrued Obligations;

(ii)A lump sum payment equal to 21 months of Executive's then-current Base Salary;

(iii)A lump sum payment equal to the Executive's full Target Bonus for the fiscal year in which the Termination Date occurs;

(iv)Provided that the Executive timely elects continued coverage under COBRA, the Company will reimburse the Executive for the monthly COBRA cost of continued health and dental coverage of the Executive and his qualified beneficiaries paid by the Executive under the health and dental plans of the Company, less the amount that the Executive would be required to contribute for health and dental coverage if the Executive were an active employee of the Company, for 21 months (or, if less, for the duration that such COBRA coverage is available to Executive). Notwithstanding the above, if the Company determines in its sole discretion that it cannot provide the COBRA benefits described herein without violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company shall in lieu thereof provide Executive with a taxable lump sum payment in an amount equal to the then-unreimbursed monthly COBRA premiums. Notwithstanding the foregoing, the Company shall

provide Executive with a taxable lump sum payment in an amount equal to the then-unreimbursed monthly COBRA premiums for months 19-21.

(v)All then-unvested Equity Awards will vest in full.

(h)*Release*. All rights, payments and benefits due to the Executive under this Section 4 (other than the Accrued Obligations) shall be conditioned on the Executive's execution of a general release of claims against the Company and its affiliates substantially in the form attached hereto as Exhibit A (the "**Release**") and on that Release becoming irrevocable within 60 days following the Termination Date. The severance described in this Section 4 (other than Accrued Obligations) shall be paid no later than the first business day following the sixtieth (60th) day following the termination of employment of Executive and in compliance with the timeframe required under Section 409A as set forth herein, and the first payment will include the payments due and owing prior to that payment date but for the application of this sentence. If the Straddle Period (as defined below) spans two (2) calendar years, then the cash payments under this Section 4 (other than Accrued Obligations) shall first be made on the first business day in the second calendar year that occurs after the expiration of the sixty (60)-day period in which the Release must be delivered and effective, as described in this Section 4. The "**Straddle Period**" shall mean the sixty (60)-day period following a termination of employment in which the Release is to be executed and become irrevocable pursuant to this Section 4.

(i)Section 280G Certain Reductions of Payments by the Company.

(1)Anything in this Agreement to the contrary notwithstanding, in the event it shall be determined that any payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (a "**Payment**"), would be nondeductible by the Company for Federal income tax purposes because of Section 280G of the Code, then the aggregate present value of amounts payable or distributable to or for the benefit of the Executive pursuant to this Agreement (such payments or distributions pursuant to this Agreement are hereinafter referred to as "**Agreement Payments**") shall be reduced to the Reduced Amount. The "**Reduced Amount**" shall be an amount expressed in present value that avoids any Payment being nondeductible by the Company because of Section 280G of the Code. To the extent necessary to avoid imposition of the Excise Tax, the amounts payable or benefits to be provided to the Executive shall be reduced such that the reduction of compensation to be provided to the Executive is minimized. In applying this principle, the reduction shall be made in a manner consistent with the requirements of Section 409A of the Code, and where two economically equivalent amounts are subject to reduction but payable at different times, such amounts shall be reduced on a pro rata basis (but not below zero). Anything to the contrary notwithstanding, if the Reduced Amount is zero and it is determined further that any Payment which is not an Agreement Payment would nevertheless be nondeductible by the Company for Federal income tax purposes because of Section 280G of the Code, then the aggregate present value of Payments which are not Agreement Payments shall also be reduced (but not below zero) to an amount expressed in present value which maximizes the aggregate present value of Payments without causing any Payment to be nondeductible by the Company because of Section 280G of the Code. If a reduction of any Payment is required pursuant to this Section 4(i), such reduction shall occur to the amounts in the order that results in the greatest economic present value of all payments and benefits actually made or provided to the Executive.

For purposes of this Section 4(i), present value shall be determined in accordance with Section 280G(d)(4) of the Code.

(2)All determinations required to be made under this Section 4(i) shall be made by a tax or compensation consulting firm of national reputation selected by the Company (the "**Consulting Firm**"), which shall provide detailed supporting calculations both to the Company and the Executive within 20 business days of the date of termination or such earlier time as is requested by the Company and an opinion to the Executive that he has substantial authority not to report any excise tax on his Federal income tax return with respect to any Payments. Any such determination by the Consulting Firm shall be binding upon the Company and the Executive. Within five business days thereafter, the Company shall pay to or distribute to or for the benefit of the Executive such amounts as are then due to the Executive under this Agreement. All fees and expenses of the Consulting Firm incurred in connection with the determinations contemplated by this Section 4(i) shall be borne by the Company.

(3)As a result of the uncertainty in the application of Section 280G of the Code at the time of the initial determination by the Consulting Firm hereunder, it is possible that Payments will have been made by the Company which should not have been made ("**Overpayment**") or that additional Payments which will not have been made by the Company could have been made ("**Underpayment**"), in each case, consistent with the calculations required to be made hereunder. In the event that the Consulting Firm, based upon the assertion of a deficiency by the Internal Revenue Service against the Executive which the Consulting Firm believes has a high probability of success, determines that an Overpayment has been made, any such Overpayment paid or distributed by the Company to or for the benefit of the Executive shall be promptly repaid to the Company by the Executive. In the event that the Consulting Firm, based upon controlling precedent or other substantial authority, determines that an Underpayment has occurred, any such Underpayment shall be promptly paid by the Company to or for the benefit of the Executive together with interest at the applicable federal rate provided for in Section 7872(f)(2) of the Code.

(j)*Cooperation*. Following the Term of Employment, the Executive shall give his assistance and cooperation willingly, upon reasonable advance notice with due consideration for his other business or personal commitments, in any matter relating to his position with the Company, or his expertise or experience as the Company may reasonably request, including his attendance and truthful testimony where deemed appropriate by the Company, with respect to any investigation or the Company's defense or prosecution of any existing or future claims or litigations or other proceedings relating to matters in which he was involved or potentially had knowledge by virtue of his employment with the Company. In no event shall his cooperation materially interfere with his services for a subsequent employer or other similar service recipient. To the extent permitted by law, the Company agrees that (i) it shall promptly reimburse the Executive for his reasonable and documented expenses in connection with his rendering assistance and/or cooperation under this Section 4(j) upon his presentation of documentation for such expenses and (ii) the Executive shall be reasonably compensated for any continued material services as required under this Section 4(j).

(k)*Return of Company Property*. Following the Termination Date, the Executive or his personal representative shall return all Company property in his possession,

including but not limited to all computer equipment (hardware and software), telephones, facsimile machines, cell phones and other communication devices, credit cards, office keys, security access cards, badges, identification cards and all copies (including drafts) of any documentation or information (however stored) relating to the business of the Company, its customers and clients or its prospective customers and clients.

(l)Compliance with Section 409A.

(i)***General***. It is the intention of both the Company and the Executive that the benefits and rights to which the Executive could be entitled pursuant to this Agreement comply with Section 409A of the Code and the Treasury Regulations and other guidance promulgated or issued thereunder ("**Section 409A**"), to the extent that the requirements of Section 409A are applicable thereto, and the provisions of this Agreement shall be construed in a manner consistent with that intention.

(ii)***Distributions on Account of Separation from Service***. If and to the extent required to comply with Section 409A, no payment or benefit required to be paid under this Agreement on account of termination of the Executive's employment shall be made unless and until the Executive incurs a "separation from service" within the meaning of Section 409A.

(iii)***Six Month Delay for Specified Employees***. If the Executive is a "specified employee" (within the meaning of Section 409A(a)(2)(B)(i) of the Code), then no payment or benefit that is payable on account of the Executive's "separation from service", as that term is defined for purposes of Section 409A, shall be made before the date that is six months after the Executive's "separation from service" (or, if earlier, the date of the Executive's death) if and to the extent that such payment or benefit constitutes deferred compensation (or may be nonqualified deferred compensation) under Section 409A and such deferral is required to comply with the requirements of Section 409A. Any payment or benefit delayed by reason of the prior sentence shall be paid out or provided in a single lump sum at the end of such required delay period in order to catch up to the original payment schedule.

(iv)***Treatment of Each Installment as a Separate Payment***. For purposes of applying the provisions of Section 409A to this Agreement, each separately identified amount to which the Executive is entitled under this Agreement shall be treated as a separate payment. In addition, any series of installment payments under this Agreement shall be treated as a right to a series of separate payments.

(v)Taxable Reimbursements and In-Kind Benefits.

(A)Any reimbursements by the Company to the Executive of any eligible expenses under this Agreement that are not excludable from the Executive's income for Federal income tax purposes (the "**Taxable Reimbursements**") shall be made by no later than the last day of the taxable year of the Executive following the year in which the expense was incurred.

(B)The amount of any Taxable Reimbursements, and the value of any in-kind benefits to be provided to the Executive, during any taxable year of the Executive

shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year of the Executive.

(C)The right to Taxable Reimbursement, or in-kind benefits, shall not be subject to liquidation or exchange for another benefit.

(vi)***Section 409A Compliance***. Notwithstanding the foregoing, the Company does not make any representation to the Executive that the payments or benefits provided under this Agreement are exempt from, or satisfy, the requirements of Section 409A, and the Company shall have no liability or other obligation to indemnify or hold harmless the Executive or any beneficiary of the Executive for any tax, additional tax, interest or penalties that the Executive or any beneficiary of the Executive may incur in the event that any provision of this Agreement, or any amendment or modification thereof, or any other action taken with respect thereto, is deemed to violate any of the requirements of Section 409A.

5.Restrictive Covenants.

(a)*Confidential Information*. The Executive shall execute and agree to be bound by the terms of the Company's Employee Invention Assignment, Confidentiality and Non-Competition Agreement (the "***EIIA***") as provided therein.

(b)*Insider Trading Policies*. Executive agrees that he shall comply with and be bound by the Company's insider trading policies with respect to the securities of the Company as now in effect or hereafter adopted or amended.

(c)*Clawback Provisions*. All incentive and equity awards and payments shall be subject to the clawback policy of the Company, as now in effect or hereafter adopted or amended, and all applicable laws and rules and regulations of the stock exchanges and public market on which the securities of the Company are traded.

(d)*Injunction*. It is recognized and hereby acknowledged by the parties hereto that a breach by the Executive of any of the covenants contained in this Section 5 or the EIIA may cause irreparable harm and damage to the Company, and its Related Entities, the monetary amount of which may be virtually impossible to ascertain. As a result, the Executive recognizes and hereby acknowledges that the Company and its Related Entities shall be entitled to seek an injunction from any court of competent jurisdiction enjoining and restraining any violation of any or all of the covenants contained in this Section 5 or the EIIA by the Executive or any of his affiliates, associates, partners or agents, either directly or indirectly, and that such right to injunction shall be cumulative and in addition to whatever other remedies the Company may possess.

6.Representations and Warranties of Executive. The Executive represents and warrants to the Company that:

(a) The Executive's employment will not conflict with or result in his breach of any agreement to which he is a party or otherwise may be bound;

(b) The Executive has not violated, and in connection with his employment with the Company will not violate, any non-solicitation, non-competition or other similar covenant or agreement of a prior employer by which he is or may be bound; and

(c) In connection with Executive's employment with the Company, he will not use any confidential or proprietary information that he may have obtained in connection with employment with any prior employer; and

7.Indemnification. Subject to limitations imposed by law, the Company shall indemnify and hold harmless the Executive to the fullest extent permitted by law from and against any and all claims, damages, expenses (including attorneys' fees), judgments, penalties, fines, settlements, and all other liabilities incurred or paid by him in connection with the investigation, defense, prosecution, settlement or appeal of any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative and to which the Executive was or is a party or is threatened to be made a party by reason of the fact that the Executive is or was an officer, employee or agent of the Company, or by reason of anything done or not done by the Executive in any such capacity or capacities, provided that the Executive acted in good faith, in a manner that was not grossly negligent or constituted willful misconduct and in a manner he reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful.

8.Definitions. When used in this Agreement, the following terms shall have the following meanings:

(a)Accrued Obligations" means:

(i)all accrued but unpaid Base Salary through the end of the Term of Employment;

(ii)any unpaid or unreimbursed expenses incurred in accordance with Company policy to the extent incurred during the Term of Employment;

(iii)any accrued but unpaid benefits provided under the Company's employee benefit plans, subject to and in accordance with the terms of those plans;

(iv)any unpaid Bonus with respect to any completed fiscal year that has ended on or prior to the end of the Term of Employment; and

(v)any accrued but unused vacation pay.

(b)"***Base Salary***" means the salary provided for in Section 3(a) hereof or any increased salary granted to Executive pursuant to Section 3(a) hereof.

(c)"***Beneficial Owner***" and "***Beneficial Ownership***" shall have the meaning ascribed to such terms in Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended.

(d)"***Board***" means the Board of Directors of the Company.

(e)"***Bonus***" means any bonus payable to the Executive pursuant to Section 3(b) hereof.

(f)"***Cause***" means any of the following:

(i)Executive's conviction of or plea of nolo contendere to a felony or to any crime involving moral turpitude;

(ii)willful misconduct or gross negligence by the Executive resulting, in either case, in material economic or reputational harm to the Company or any of Related Entities;

(iii)a willful failure by the Executive to carry out the reasonable and lawful directions of the Board and failure by the Executive to remedy the failure within thirty (30) days after receipt of written notice of same, by the Board;

(iv)fraud, embezzlement, theft or dishonesty of a material nature by the Executive against the Company or any Related Entity, or a willful material violation by the Executive of a policy or procedure of the Company or any Related Entity, resulting, in any case, in material, reputational or economic harm to the Company or any Related Entity; or

(v)a willful material breach by the Executive of this Agreement and failure by the Executive to remedy the material breach within 30 days after receipt of written notice of same, by the Board.

(g)"***Change in Control***" means the occurrence of any of the following events: (i) any Person becomes the Beneficial Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total voting power represented by the Company's then-outstanding voting securities; provided, however, that for purposes of this subclause (i) the acquisition of additional securities by any one Person who is considered to own more than fifty percent (50%) of the total voting power of the securities of the Company will not be considered a Change in Control; (ii) the consummation of the sale or disposition by the Company of all or substantially all of the Company's assets; (iii) the consummation of a merger or consolidation of the Company with any other corporation, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) at least fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation; or (iv) a change in the effective control of the Company that occurs on the date that a majority of members of the Board is replaced during any twelve (12) month period by members of the Board whose appointment or election is not endorsed by a majority of the members of the Board prior to the date of the appointment or election. For purpose of this subclause (iv), if any Person is considered to be in effective control of the Company, the acquisition of additional control of the Company by the same Person will not be considered a Change in Control. For purposes of this definition, Persons will be considered to be acting as a group if they are owners of a corporation that enters into a merger, consolidation, purchase or acquisition of stock, or similar business transaction with the Company.

(h)"***COBRA***" means the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended from time to time.

(i)"***Code***" means the Internal Revenue Code of 1986, as amended.

(j)"***Commencement Date***" means the date of this Agreement.

(k)"***Disability***" means the Executive's inability, or failure, to perform the essential functions of his position, with or without reasonable accommodation, for any period of six months or more in any 12 month period, by reason of any medically determinable physical or mental impairment.

(l)"***Equity Awards***" means any stock options, restricted stock, restricted stock units, stock appreciation rights, phantom stock or other equity based awards granted by the Company to the Executive.

(m)"***Excise Tax***" means any excise tax imposed by Section 4999 of the Code, together with any interest and penalties imposed with respect thereto, or any interest or penalties are incurred by the Executive with respect to any such excise tax.

(n)"***Good Reason***" means the occurrence of any of the following events or conditions, without the Executive's express written consent:

(i)a material diminution in the Executive's authority, duties, or responsibilities, provided, however, that the mere acquisition or merger of the Company by itself shall not constitute a material diminution in the Executive's authority, duties, or responsibilities;

(ii)a material reduction by the Company in the Executive's annual Base Salary (which for purposes hereof is deemed to constitute a reduction of greater than 10%, unless such reduction applies as part of a salary reduction program and such program includes similar reductions to all of the Executive's direct reports); or

(iii)the relocation of the Executive's principal place of employment to a location more than 50 miles from the Executive's principal place of employment immediately prior to the Executive's termination.

With respect to each of subsection (i), (ii) and (iii) above, the Executive must provide notice to the Company of the condition giving rise to "Good Reason" within 30 days of the initial existence of such condition, and the Company will have 30 days following such notice to remedy such condition. The Executive must resign the Executive's employment no later than 30 days following the Company's failure to cure the Good Reason or written notice to the Executive that it will decline to do so.

(o)"***Group***" shall have the meaning ascribed to such term in Section 13(d) of the Securities Exchange Act of 1934.

(p)"***Person***" shall have the meaning ascribed to such term in Section 3(a)(9) of the Securities Exchange Act of 1934 and used in Sections 13(d) and 14(d) thereof.

(q)"***Related Entity***" means any Person controlling, controlled by or under common control with the Company or any of its subsidiaries. For this purpose, the terms "controlling," "controlled by" and "under common control with" mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, as trustee or executor, by contract or otherwise, including (without limitation) the ownership, directly or indirectly, of securities having the power to elect a majority of the board of directors or similar body governing the affairs of such Person.

(r)"***Target Bonus***" has the meaning described in Section 3(b).

(s)"***Term of Employment***" means the period during which the Executive shall be employed by the Company pursuant to the terms of this Agreement, which period shall begin on the Commencement Date and continue until terminated in accordance with Section 4 hereof.

(t)"***Termination Date***" means the date on which the Term of Employment ends.

9.Miscellaneous Provisions.

(a)*Taxes*. All payments or transfers of property made by the Company to the Executive or his estate or beneficiaries shall be subject to the withholding of such amounts relating to taxes as the Company may reasonably determine it should withhold pursuant to any applicable law or regulation.

(b)*Assignment*. The Company shall have the right to assign this Agreement and its rights and obligations hereunder in whole, but not in part, to any corporation or other entity with or into which the Company may hereafter merge or consolidate or to which the Company may transfer all or substantially all of its assets, if in any such case said corporation or other entity shall by operation of law or expressly in writing assume all obligations of the Company hereunder as fully as if it had been originally made a party hereto, but may not otherwise assign this Agreement or its rights and obligations hereunder. The Executive may not assign or transfer this Agreement or any rights or obligations hereunder.

(c)*Governing Law*. Except as expressly set forth herein, this letter agreement and the rights and obligations of the parties hereto shall be construed in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to the principles of conflict of laws.

(d)*Arbitration and Class Action Waiver*. Executive and the Company agree to submit to mandatory binding arbitration any and all claims arising out of or related to Executive's employment with the Company and the termination thereof, including, but not limited to, claims for unpaid wages, wrongful termination, torts, stock or stock options or other ownership interest in the Company, and/or discrimination (including harassment), except as set forth below, based upon any federal, state or local ordinance, statute, regulation or constitutional provision except that each party may, at its, his or her option, seek injunctive relief in court related to the improper use, disclosure or misappropriation of a party's private, proprietary, confidential or trade secret information (collectively, "**Arbitrable Claims**"). Further, to the fullest extent permitted by law, Executive and the Company agree that no class or collective actions can be asserted in arbitration or otherwise. All claims, whether in arbitration or otherwise, must be brought solely in Executive's

or the Company's individual capacity, and not as a plaintiff or class member in any purported class or collective proceeding.

THE PARTIES HEREBY WAIVE ANY RIGHTS THEY MAY HAVE TO TRIAL BY JURY IN REGARD TO ARBITRABLE CLAIMS. THE PARTIES FURTHER WAIVE ANY RIGHTS THEY MAY HAVE TO PURSUE OR PARTICIPATE IN A CLASS OR COLLECTIVE ACTION PERTAINING TO ANY ARBITRABLE CLAIMS BETWEEN YOU AND THE COMPANY.

Notwithstanding anything to the contrary herein, nothing in this Arbitration and Class Action Waiver section restricts Executive's right to pursue claims in court (a) on a representative action basis under applicable law or (b) for any alleged sexual harassment or any alleged unlawful discriminatory practices related to sexual harassment.

This Agreement does not restrict Executive's right to file administrative claims Executive may bring before any government agency where, as a matter of law, the parties may not restrict the employee's ability to file such claims (including, but not limited to, the National Labor Relations Board, the Equal Employment Opportunity Commission and the Department of Labor). However, the parties agree that, to the fullest extent permitted by law, arbitration shall be the exclusive remedy for the subject matter of such administrative claims. The arbitration shall be conducted in Boston, Massachusetts through JAMS before a single neutral arbitrator, in accordance with the JAMS employment arbitration rules then in effect. The JAMS rules may be found and reviewed at http://www.jamsadr.com/rules-employment-arbitration. If Executive is unable to access these rules, please let the Company know and Executive will be provided with a hardcopy. The arbitrator shall issue a written decision that contains the essential findings and conclusions on which the decision is based. Executive and the Company agree that this Arbitration and Class Action Waiver Provision shall be governed by the Federal Arbitration Act. Should any portion of this provision be found unenforceable, it shall be severed and the remaining provisions shall remain in full force and effect.

(e)*Entire Agreement*. This Agreement, together with the exhibit attached hereto, constitutes the entire agreement between the patties hereto with respect to the subject matter hereof and, upon its effectiveness, shall supersede all prior agreements, understandings and arrangements, both oral and written, between the Executive and the Company (or any of its Related Entities) with respect to such subject matter. This Agreement may not be modified in any way unless by a written instrument signed by both the Company and the Executive.

(f)*Notices*. All notices required or permitted to be given hereunder shall be in writing and shall be personally delivered by courier, sent by registered or certified mail, return receipt requested or sent by confirmed facsimile transmission addressed as set forth herein. Notices personally delivered, sent by facsimile or sent by overnight courier shall be deemed given on the date of delivery and notices mailed in accordance with the foregoing shall be deemed given upon receipt by the addressee, as evidenced by the return receipt thereof. Notice shall be sent (i) if to the Company, addressed to the Company's headquarters, Attention: the Company's Board, and (ii) if to the Executive, to his address as reflected on the payroll records of the Company, or to such other address as either party shall request by notice to the other in accordance with this provision.

(g)*Benefits; Binding Effect*. This Agreement shall be for the benefit of and binding upon the parties hereto and their respective heirs, personal representatives, legal representatives, successors and, where permitted and applicable, assigns, including, without limitation, any successor to the Company, whether by merger, consolidation, sale of stock, sale of assets or otherwise.

(h)*Right to Consult with Counsel*. The Executive acknowledges having read and considered all of the provisions of this Agreement carefully, and having had the opportunity to consult with counsel of his own choosing, and, given this, the Executive agrees that the obligations created hereby are not unreasonable.

(i)*Severability*. The invalidity of any one or more of the words, phrases, sentences, clauses, provisions, sections or articles contained in this Agreement shall not affect the enforceability of the remaining portions of this Agreement or any part thereof, all of which are inserted conditionally on their being valid in law, and, in the event that any one or more of the words, phrases, sentences, clauses, provisions, sections or articles contained in this Agreement shall be declared invalid, this Agreement shall be construed as if such invalid word or words, phrase or phrases, sentence or sentences, clause or clauses, provisions or provisions, section or sections or article or articles had not been inserted. If such invalidity is caused by length of time or size of area, or both, the otherwise invalid provision will be considered to be reduced to a period or area which would cure such invalidity.

(j)*Waivers*. The waiver by either party hereto of a breach or violation of any term or provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or violation.

(k)*Damages; Attorneys' Fees*. Nothing contained herein shall be construed to prevent the Company or the Executive from seeking and recovering from the other damages sustained by either or both of them as a result of its or his breach of any term or provision of this Agreement. Each party shall bear its own costs and attorneys' fees.

(l)*No Set-off or Mitigation*. The Company's obligation to make the payments provided for in this Agreement and otherwise to perform its obligations hereunder shall not be affected by any set off, counterclaim, recoupment, defense or other claim, right or action which the Company may have against the Executive or others. In the event of any termination of the Executive's employment under this Agreement, he shall be under no obligation to seek other employment or otherwise in any way to mitigate the amount of any payment provided for hereunder.

(m)*Section Headings*. The article, section and paragraph headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

(n)*No Third Party Beneficiary*. The Related Entities are intended third party beneficiaries of this Agreement. Otherwise, nothing expressed or implied in this Agreement is intended, or shall be construed, to confer upon or give any person other than the Company, the

parties hereto and their respective heirs, personal representatives, legal representatives, successors and permitted assigns, any rights or remedies under or by reason of this Agreement.

(o)*Counterparts*. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument and agreement.

[Signature Page to Amended and Restated Executive Employment Agreement Follows]

IN WITNESS WHEREOF, the undersigned have executed this Agreement on the date first above written.

Company	**Executive**
KalVista Pharmaceuticals, Inc.	
/s/ Albert Cha	/s/ Benjamin L. Palleiko
Print Name: Albert Cha	Benjamin L. Palleiko
Title: Director	

[Signature Page to Amended and Restated Executive Employment Agreement]

Exhibit A

General Release of Claims

1.Benjamin L. Palleiko ("**Executive**"), for himself and his family, heirs, executors, administrators, legal representatives and their respective successors and assigns, in exchange for the consideration received pursuant to Section [4(e)] [4(g)] of the Amended and Restated Executive Employment Agreement (the "**Severance Benefits**") to which this release is attached as Exhibit B (the "**Employment Agreement**"), does hereby release and forever discharge KalVista Pharmaceuticals, Inc. (the "**Company**"), its subsidiaries, affiliated companies, successors and assigns, and its current or former directors, officers, employees, shareholders or agents in such capacities (collectively with the Company, the "**Released Partie**s") from any and all actions, causes of action, suits, controversies, claims and demands whatsoever, for or by reason of any matter, cause or thing whatsoever, whether known or unknown including, but not limited to, all claims under any applicable laws arising under or in connection with Executive's employment or termination thereof, whether for tort, breach of express or implied employment contract, wrongful discharge, intentional infliction of emotional distress, or defamation or injuries incurred on the job or incurred as a result of loss of employment. Without limiting the generality of the release provided above, Executive expressly waives any and all claims under Age Discrimination in Employment Act ("**ADEA**") that he may have as of the date hereof. Executive further understands that, by signing this General Release of Claims, he is in fact waiving, releasing and forever giving up any claim under the ADEA as well as all other laws within the scope of this paragraph 1 that may have existed on or prior to the date hereof. Notwithstanding anything in this paragraph 1 to the contrary, this General Release of Claims shall not apply to (i) any rights to receive any payments or benefits to which the Executive is entitled under COBRA, (ii) any rights or claims that may arise as a result of events occurring after the date this General Release of Claims is executed, (iii) any indemnification and advancement rights Executive may have as a former employee, officer or director of the Company or its subsidiaries or affiliated companies (including any rights under Section 7 of the Employment Agreement), (iv) any claims for benefits under any directors' and officers' liability policy maintained by the Company or its subsidiaries or affiliated companies in accordance with the terms of such policy, (v) rights to vested benefits under the Company's 401(k) plan, and (vi) any rights as a holder of equity securities of the Company.

2.Executive understands that nothing in this Release shall in any way limit or prohibit Executive from engaging in any Protected Activity. For purposes of this Release, "**Protected Activity**" shall mean filing a charge, complaint, or report with, or otherwise communicating, cooperating, or participating in any investigation or proceeding that may be conducted by, any federal, state or local government agency or commission, including the Securities and Exchange Commission, the Equal Employment Opportunity Commission, the Occupational Safety and Health Administration, and the National Labor Relations Board ("**Government Agencies**"). Executive understands that in connection with such Protected Activity, Executive is permitted to disclose documents or other information as permitted by law, and without giving notice to, or receiving authorization from, the Company. Notwithstanding the foregoing, Executive agrees to take all reasonable precautions to prevent any unauthorized use or disclosure of any information that may constitute Company confidential information to any parties other than the Government Agencies. Executive further understands that "Protected Activity" does not include the disclosure of any Company attorney-client privileged communications. In addition, pursuant to the Defend

Trade Secrets Act of 2016, Executive is notified that an individual will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (i) is made in confidence to a federal, state, or local government official (directly or indirectly) or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if (and only if) such filing is made under seal. In addition, an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the individual's attorney and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal and does not disclose the trade secret, except pursuant to court order. This Release does not limit Executive's right to receive an award for information provided to any Government Agencies.

3.Executive represents that he has not filed against the Released Parties any complaints, charges, or lawsuits arising out of his employment, or any other matter arising on or prior to the date of this General Release of Claims, and covenants and agrees that he will never individually or with any person file, or commence the filing of any lawsuits, complaints or proceedings with any governmental agency, or against the Released Parties with respect to any of the matters released by Executive pursuant to paragraph 1 hereof; provided, that nothing herein shall prevent Executive from filing a charge or complaint with the Equal Employment Opportunity Commission ("**EEOC**") or similar federal or state agency or the Executive's ability to participate in any investigation or proceeding conducted by such agency. Nothing in this paragraph shall serve to limit, restrain or impair Executive's rights under paragraph 2 above.

4.Executive acknowledges that, in the absence of his execution of this General Release of Claims, the Severance Benefits would not otherwise be due to him.

5.Executive acknowledges and agrees that he received adequate consideration in exchange for agreeing to the covenants contained in Section 5 of the Employment Agreement and the EIAA (as defined therein), that such covenants remain reasonable and necessary to protect the legitimate business interests of the Company and its affiliates and that he will continue to comply with those covenants.

6.Executive hereby acknowledges that the Company has informed him that he has up to 21 days to sign this General Release of Claims and he may knowingly and voluntarily waive that 21 day period by signing this General Release of Claims earlier. Executive also understands that he shall have seven days following the date on which he signs this General Release of Claims within which to revoke it by providing a written notice of his revocation to the Company.

7.Executive acknowledges and agrees that this General Release of Claims will be governed by and construed and enforced in accordance with the internal laws of the State of Massachusetts applicable to contracts made and to be performed entirely within such State.

8.Executive acknowledges that he has read this General Release of Claims, that he has been advised that he should consult with an attorney before he executes this general release of claims, and that he understands all of its terms and executes it voluntarily and with full knowledge of its significance and the consequences thereof.

9.This General Release of Claims shall become irrevocable on the eighth day following Executive's execution of this General Release of Claims, unless previously revoked in accordance with paragraph 6, above.

Intending to be legally bound hereby, Executive has executed this General Release of Claims on _____, 20__.

Executive

Benjamin L. Palleiko

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 CH GmbH	Switzerland
KalVista Pharmaceuticals Japan K.K.	Japan

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in 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 and 333-280579 on Form S-8 of our report dated July 11, 2024, relating to the financial statements of KalVista Pharmaceuticals, Inc. appearing in this Annual Report on Form 10-K of KalVista Pharmaceuticals, Inc. for the year ended April 30, 2024.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
July 11, 2024

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 11, 2024

By: /s/ Benjamin L. Palleiko
Benjamin L Palleiko
Chief Executive Officer
(Principal Executive, 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, 2024 (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 11, 2024

By: /s/ Benjamin L. Palleiko
Benjamin L. Palleiko
Chief Executive Officer
(Principal Executive, Financial and Accounting Officer)

Exhibit 97.1

KalVista Pharmaceuticals, Inc.

Compensation Recovery Policy

(Effective December 1, 2023)

The Board has determined that it is in the best interests of the Company and its stockholders to adopt this Policy enabling the Company to recover from specified current and former Company executives certain incentive-based compensation in the event of an accounting restatement resulting from material noncompliance with any financial reporting requirements under the federal securities laws. Capitalized terms are defined in Section 14.

This Policy is designed to comply with Rule 10D-1 of the Exchange Act and shall become effective on the Effective Date and shall apply to Incentive-Based Compensation Received by Covered Persons on or after the Listing Rule Effective Date.

1.Administration

This Policy shall be administered by the Administrator. The Administrator is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. The Administrator may retain, at the Company's expense, outside legal counsel and such compensation, tax or other consultants as it may determine are advisable for the purpose of administering this Policy.

2.Covered Persons and Applicable Compensation

This Policy applies to any Incentive-Based Compensation Received by a person (a) after beginning service as a Covered Person; (b) who served as a Covered Person at any time during the performance period for that Incentive-Based Compensation; and (c) was a Covered Person during the Clawback Period.

However, recovery is not required with respect to:

i.Incentive-Based Compensation Received prior to an individual becoming a Covered Person, even if the individual served as a Covered Person during the Clawback Period.

ii.Incentive-Based Compensation Received prior to the Listing Rule Effective Date.

iii.Incentive-Based Compensation Received prior to the Clawback Period.

iv.Incentive-Based Compensation Received while the Company did not have a class of listed securities on a national securities exchange or a national securities association, including the Exchange.

The Administrator will not consider the Covered Person's responsibility or fault or lack thereof in enforcing this Policy with respect to recoupment under the Final Rules.

3.Triggering Event

Subject to and in accordance with the provisions of this Policy, if there is a Triggering Event, the Administrator shall require a Covered Person to reimburse or forfeit to the Company the Recoupment Amount applicable to such Covered Person. A Company's obligation to recover the Recoupment Amount is not dependent on if or when the restated financial statements are filed.

4.Calculation of Recoupment Amount

The Recoupment Amount will be calculated in accordance with the Final Rules, as provided in the Calculation Guidelines attached hereto as Exhibit B.

5.Method of Recoupment

Subject to compliance with the Final Rules and applicable law, the Administrator will determine, in its sole discretion, the method for recouping the Recoupment Amount hereunder which may include, without limitation:

i. Requiring reimbursement or forfeiture of the pre-tax amount of cash Incentive-Based Compensation previously paid;

ii. Offsetting the Recoupment Amount from any compensation otherwise owed by the Company to the Covered Person, including without limitation, any prior cash incentive payments, executive retirement benefits, wages, equity grants or other amounts payable by the Company to the Covered Person in the future;

iii. Seeking recovery of any gain realized on the vesting, exercise, settlement, cash sale, transfer or other disposition of any equity-based awards; and/or

iv. Taking any other remedial and recovery action permitted by law, as determined by the Administrator.

6.Arbitration

To the fullest extent permitted by law, any disputes under this Policy shall be submitted to mandatory binding arbitration (the "***Arbitrable Claims***"), governed by the Federal Arbitration Act (the "***FAA***"). Further, to the fullest extent permitted by law, no class or collective actions can be asserted in arbitration or otherwise. All claims, whether in arbitration or otherwise, must be brought solely in the Covered Person's individual capacity, and not as a plaintiff or class member in any purported class or collective proceeding.

SUBJECT TO THE ABOVE PROVISO, ANY RIGHTS THAT A COVERED PERSON MAY HAVE TO TRIAL BY JURY IN REGARD TO ARBITRABLE CLAIMS ARE WAIVED. ANY RIGHTS THAT A COVERED PERSON MAY HAVE TO PURSUE OR PARTICIPATE IN A

CLASS OR COLLECTIVE ACTION PERTAINING TO ANY CLAIMS BETWEEN A COVERED PERSON AND THE COMPANY ARE WAIVED.

The Covered Person is not restricted from filing administrative claims that may be brought before any government agency where, as a matter of law, the Covered Person's ability to file such claims may not be restricted. However, to the fullest extent permitted by law, arbitration shall be the exclusive remedy for the subject matter of such administrative claims. The arbitration shall be conducted in Cambridge, MA through JAMS before a single neutral arbitrator, in accordance with the JAMS Comprehensive Arbitration Rules and Procedures then in effect, provided however, that the FAA, including its procedural provisions for compelling arbitration, shall govern and apply to this Arbitration provision. The arbitrator shall issue a written decision that contains the essential findings and conclusions on which the decision is based. If, for any reason, any term of this Arbitration provision is held to be invalid or unenforceable, all other valid terms and conditions herein shall be severable in nature and remain fully enforceable.

7.Recovery Process; Impracticability

Actions by the Administrator to recover the Recoupment Amount will be reasonably prompt.

The Administrator must cause the Company to recover the Recoupment Amount unless the Administrator determines that recovery is impracticable and one of the following conditions is met:

i.The direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered; before concluding that it would be impracticable to recover any amount of erroneously awarded Incentive-Based Compensation based on expense of enforcement, the Company must make a reasonable attempt to recover such erroneously awarded Incentive-Based Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange;

ii.Recovery would violate home country law where that law was adopted prior to November 28, 2022; before concluding that it would be impracticable to recover any amount of erroneously awarded Incentive-Based Compensation based on violation of home country law, the Company must obtain an opinion of home country counsel, acceptable to the Exchange, that recovery would result in such a violation, and must provide such opinion to the Exchange; or

iii.Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

8.Non-Exclusivity

The Administrator intends that this Policy will be applied to the fullest extent of the law. Without limitation to any broader or alternate clawback authorized in any written document with a Covered Person, (i) the Administrator may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Person to agree to abide by the terms of this Policy, and (ii) this Policy will nonetheless apply to Incentive-Based Compensation as required by the Final Rules, whether or not specifically referenced in those arrangements. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies or regulations available or applicable to the Company (including SOX 304). If recovery is required under both SOX 304 and this Policy, any amounts recovered pursuant to SOX 304 may be credited toward the amount recovered under this Policy, or vice versa.

9.No Indemnification

The Company shall not indemnify any Covered Persons against (i) the loss of erroneously awarded Incentive-Based Compensation or any adverse tax consequences associated with any incorrectly awarded Incentive-Based Compensation or any recoupment hereunder, or (ii) any claims relating to the Company enforcement of its rights under this Policy. For the avoidance of doubt, this prohibition on indemnification will also prohibit the Company from reimbursing or paying any premium or payment of any third-party insurance policy to fund potential recovery obligations obtained by the Covered Person directly. No Covered Person will seek or retain any such prohibited indemnification or reimbursement.

Further, the Company shall not enter into any agreement that exempts any Incentive-Based Compensation from the application of this Policy or that waives the Company's right to recovery of any erroneously awarded Incentive-Based Compensation and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date).

10.Covered Person Acknowledgement and Agreement

All Covered Persons subject to this Policy must acknowledge their understanding of, and agreement to comply with, the Policy by executing the certification attached hereto as Exhibit A. **Notwithstanding the foregoing, this Policy will apply to Covered Persons whether or not they execute such certification.**

11.Successors

This Policy shall be binding and enforceable against all Covered Persons and their beneficiaries, heirs, executors, administrators or other legal representatives and shall inure to the benefit of any successor to the Company.

12.Interpretation of Policy

To the extent there is any ambiguity between this Policy and the Final Rules, this Policy shall be interpreted so that it complies with the Final Rules. If any provision of this Policy, or the application of such provision to any Covered Person or circumstance, shall be held invalid, the remainder of this Policy, or the application of such provision to Covered Persons or circumstances other than those as to which it is held invalid, shall not be affected thereby.

In the event any provision of this Policy is inconsistent with any requirement of any Final Rules, the Administrator, in its sole discretion, shall amend and administer this Policy and bring it into compliance with such rules.

Any determination under this Policy by the Administrator shall be conclusive and binding on the applicable Covered Person. Determinations of the Administrator need not be uniform with respect to Covered Persons or from one payment or grant to another.

13.Amendments; Termination

The Administrator may make any amendments to this Policy as required under applicable law, rules and regulations, or as otherwise determined by the Administrator in its sole discretion.

The Administrator may terminate this Policy at any time.

14.Definitions

"***Administrator***" means the Compensation Committee of the Board, or in the absence of a committee of independent directors responsible for executive compensation decisions, a majority of the independent directors serving on the Board.

"***Board***" means the Board of Directors of the Company.

"***Clawback Measurement Date***" is the earlier to occur of:

i.The date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an accounting restatement as described in this Policy; or

ii.The date a court, regulator, or other legally authorized body directs the Company to prepare an accounting restatement as described in this Policy.

"***Clawback Period***" means the three (3) completed fiscal years immediately prior to the Clawback Measurement Date and any transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year (that results from a change in the Company's fiscal year) within or immediately following such three (3)-year period; provided that any transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of 9 to 12 months will be deemed a completed fiscal year.

"***Company***" means KalVista Pharmaceuticals, Inc., a Delaware corporation, or any successor corporation.

"***Covered Person***" means any Executive Officer (as defined in the Final Rules), including, but not limited to, those persons who are or have been determined to be "officers" of the Company within the meaning of Section 16 of Rule 16a-1(f) of the rules promulgated under the Exchange Act, and "executive officers" of the Company within the meaning of Item 401(b) of Regulation S-K, Rule 3b-7 promulgated under the Exchange Act, and Rule 405 promulgated under the Securities Act of 1933, as amended; provided that the Administrator may identify additional employees who shall be treated as Covered Persons for the purposes of this Policy with prospective effect, in accordance with the Final Rules.

"***Effective Date***" means December 1, 2023.

"***Exchange***" means the Nasdaq Global Market or any other national securities exchange or national securities association in the United States on which the Company has listed its securities for trading.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Final Rules***" means the final rules promulgated by the SEC under Section 954 of the Dodd-Frank Act, Rule 10D-1 and Exchange listing standards, as may be amended from time to time.

"***Financial Reporting Measure***" are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and TSR are also financial reporting measures. A financial reporting measure need not be presented within the financial statements or included in a filing with the SEC.

"***Incentive-Based Compensation***" means compensation that is granted, earned or vested based wholly or in part on the attainment of any Financial Reporting Measure. Examples of "Incentive-Based Compensation" include, but are not limited to: non-equity incentive plan awards that are earned based wholly or in part on satisfying a Financial Reporting Measure performance goal; bonuses paid from a "bonus pool," the size of which is determined based wholly or in part on satisfying a Financial Reporting Measure performance goal; other cash awards based on satisfaction of a Financial Reporting Measure performance goal; restricted stock, restricted stock units, performance share units, stock options, and SARs that are granted or become vested based wholly or in part on satisfying a Financial Reporting Measure goal; and proceeds received upon the sale of shares acquired through an incentive plan that were granted or vested based wholly or in part on satisfying a Financial Reporting Measure goal. "Incentive-Based Compensation" excludes, for example, time-based awards such as stock options or restricted stock units that are

granted or vest *solely* upon completion of a service period; awards based on non-financial reporting strategic or operating metrics such as fundraising or spending targets, the consummation of a merger or achievement of non-financial reporting business goals; service-based retention bonuses; discretionary compensation; and salary.

"***Listing Rule Effective Date***" means the effective date of the listing standards of the Exchange on which the Company's securities are listed.

"***Policy***" means this Compensation Recovery Policy.

Incentive-Based Compensation is deemed "***Received***" in the Company's fiscal period during which the relevant Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, irrespective of whether the payment or grant occurs on a later date or if there are additional vesting or payment requirements, such as time-based vesting or certification or approval by the Compensation Committee or Board, that have not yet been satisfied.

"***Recoupment Amount***" means the amount of Incentive-Based Compensation Received by the Covered Person based on the financial statements prior to the restatement that exceeds the amount such Covered Person would have received had the Incentive-Based Compensation been determined based on the financial restatement, computed without regard to any taxes paid (*i.e*., gross of taxes withheld).

"***SARs***" means stock appreciation rights.

"***SEC***" means the U.S. Securities and Exchange Commission.

"***SOX 304***" means Section 304 of the Sarbanes-Oxley Act of 2002.

"***Triggering Event***" means any event in which the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***TSR***" means total stockholder return.

EXHIBIT A

Certification

I certify that:

1.I have read and understand the Company's Compensation Recovery Policy (the "***Policy***"). I understand that the General Counsel or Chief Financial Officer is available to answer any questions I have regarding the Policy.

2.I understand that the Policy applies to all of my existing and future compensation-related agreements with the Company, whether or not explicitly stated therein.

3.I agree that notwithstanding the Company's certificate of incorporation, bylaws, and any agreement I have with the Company, including any indemnity agreement I have with the Company, I will not be entitled to, and will not seek indemnification from the Company for, any amounts recovered or recoverable by the Company in accordance with the Policy.

4.I understand and agree that in the event of a conflict between the Policy and the foregoing agreements and understandings on the one hand, and any prior, existing or future agreement, arrangement or understanding, whether oral or written, with respect to the subject matter of the Policy and this Certification, on the other hand, the terms of the Policy and this Certification shall control, and the terms of this Certification shall supersede any provision of such an agreement, arrangement or understanding to the extent of such conflict with respect to the subject matter of the Policy and this Certification.

5.I agree to abide by the terms of the Policy, including, without limitation, by returning any erroneously awarded Incentive-Based Compensation to the Company to the extent required by, and in a manner permitted by, the Policy.

Signature: __

Name: ___

Title: ___

Date: ___

EXHIBIT B

Calculation Guidelines

Unless determined otherwise by the Administrator and in accordance with the Final Rules, for purposes of calculating the Recoupment Amount:

i.For cash awards not paid from bonus pools, the erroneously awarded compensation is the difference between the amount of the cash award (whether payable as a lump sum or over time) that was received and the amount that should have been received applying the restated Financial Reporting Measure.

ii.For cash awards paid from bonus pools, the erroneously awarded compensation is the pro rata portion of any deficiency that results from the aggregate bonus pool that is reduced based on applying the restated Financial Reporting Measure.

iii.For equity awards, if the shares, options, restricted stock units, or SARs are still held at the time of recovery, the erroneously awarded compensation is the number of such securities received in excess of the number that should have been received applying the restated Financial Reporting Measure (or the value of that excess number). If the options or SARs have been exercised, but the underlying shares have not been sold, the erroneously awarded compensation is the number of shares underlying the excess options or SARs (or the value thereof). If the underlying shares have been sold, the Company may recoup proceeds received from the sale of shares.

iv.For Incentive-Based Compensation based on stock price or TSR, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement:

a.The amount must be based on a reasonable estimate of the effect of the accounting restatement on the stock price or TSR upon which the Incentive-Based Compensation was Received; and

b.The Company must maintain documentation of the determination of that reasonable estimate and the Company must provide such documentation to the Exchange in all cases.