UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended April 30, 2025
OR

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

Commission File Number 001-36830

KalVista Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its Charter)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of common stock held by non-affiliates of the registrant calculated based on the closing price of $10.27 of the registrant's common stock as reported on The Nasdaq Global Market on October 31, 2024, the last business day of the registrant's most recently completed second quarter, was approximately $440,082,646.

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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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

Our Company

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

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

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

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

Key Updates

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

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

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

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

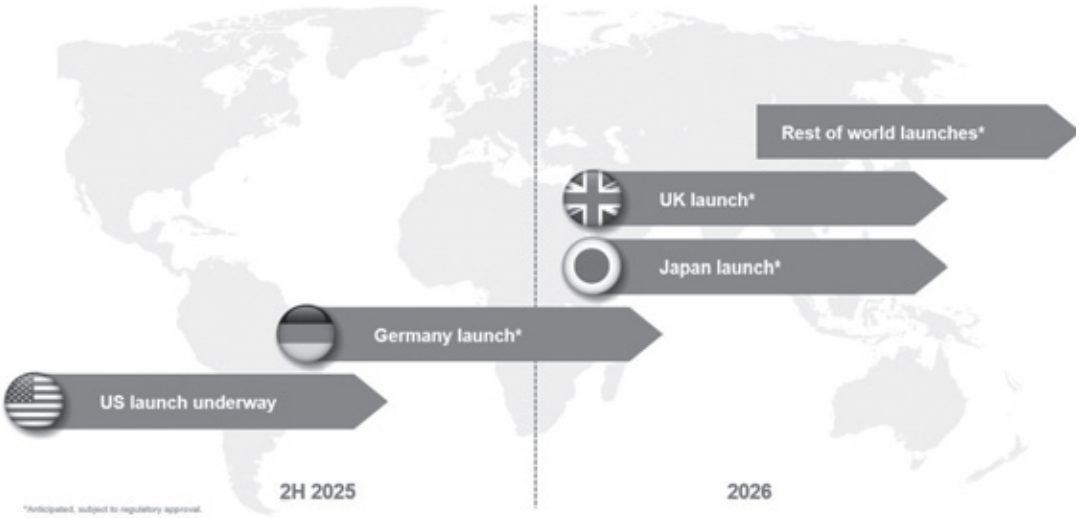
Our Strategy

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

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

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

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



Plasma Kallikrein in HAE

Plasma kallikrein is a serine protease enzyme that is a key mediator of inflammation and edema. The body modulates the downstream inflammatory effects of plasma kallikrein through a circulating inhibitor protein called C1-esterase inhibitor ("C1-INH"). Most patients with HAE have a genetic mutation that leads to C1-INH deficiency, which results in an inability to control activated plasma kallikrein in affected tissues. This excessive activation leads to inflammation, edema, and pain. The majority of the approved therapies in HAE today inhibit plasma kallikrein in some manner.

Hereditary Angioedema

Disease Overview

HAE is a rare and potentially life-threatening genetic condition that occurs in about 1 in 35,000 to 1 in 50,000 people, according to published information from an HAE patient advocacy group. Excessive plasma kallikrein activation that is not sufficiently controlled by C1-INH leads to HAE attacks, which can vary with regard to the affected tissue or organ and severity. HAE attacks include episodes of intense swelling usually in the skin, gastrointestinal tract or airways. They often lead to temporary disfiguration of various body parts including the hands, feet, face, body trunk, and genitals. In addition, patients often have bouts of excruciating abdominal pain, nausea and vomiting that is caused by swelling in the intestinal wall. Airway swelling is particularly dangerous and can lead to death by asphyxiation. Untreated attacks can be functionally disabling and commonly take days to fully resolve.

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

HAE is an autosomal dominant disease, meaning that a defect in only one copy of the gene leads to symptoms and that it occurs at similar rates in both males and females. The most common cause of HAE is a defect or mutation in the gene responsible for the production of C1-INH. C1-INH is a natural plasma-borne protein that is an inhibitor of multiple serine proteases in both the complement and kallikrein-kinin systems. C1-INH is the predominant physiological inhibitor of plasma kallikrein, and thereby suppresses the generation of bradykinin, a potent hormone produced by plasma kallikrein, that activates its receptors on blood vessels to increase vascular leakage. Uncontrolled plasma kallikrein activity leads to the edema that is the hallmark of HAE.

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

HAE Treatment Landscape

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

EKTERLY (sebetralstat)

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

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

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

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

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

Clinical Trials

KONFIDENT-KID

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

KONFIDENT-S

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

Factor XIIa

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

Commercial Operations

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

License, Supply and Distribution Agreement

Kaken Agreement

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

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

Competition

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product and product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are marketing our product and developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches.

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

Intellectual Property

Our success substantially depends on our ability to obtain and maintain patents and other forms of intellectual property rights for our products and product candidates, methods used to manufacture our product candidates and methods for treating patients using our products and product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. Our patent portfolio includes patents and patent applications covering plasma kallikrein inhibitors (the "plasma kallikrein portfolio"), and patent applications covering FXIIa inhibitors (the "FXIIa portfolio").

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

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

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

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

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

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

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

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

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

Government Regulation and Product Approval

Government authorities in the U.S., at the federal, state and local level, and in other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the U.S. and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

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

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves nonclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application ("IND"), which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically take many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with Good Clinical Practice ("GCP") an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; and (iii) under protocols detailing the objectives of the trial and the criteria to be evaluated. Each protocol involving testing on U.S. healthy volunteers or patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

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

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

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

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

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

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

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

Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Changes to some of the conditions established in an approved NDA, including changes in indications, product labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or supplement to an approved NDA, before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing original NDAs.

Orphan Drug Designation

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

Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the drug and its potential orphan disease use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active moiety to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product in the approved indication.

During the seven-year marketing exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. A product can be considered clinically superior if it is safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA user fee.

Fast Track Designation and Priority Review

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

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

Disclosure of Clinical Trial Information

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

Pediatric Information

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

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

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities.

Adverse event reporting and submission of periodic safety summary reports is required following FDA approval of an NDA. The FDA also may require nonclinical or clinical postmarketing requirements, REMS, or surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. Sponsors may also agree to conduct nonclinical or clinical postmarketing commitments after approval. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects a drug's manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with required regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The Hatch-Waxman Amendments

Orange Book Listing

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

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

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

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

Exclusivity

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

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

Patent Term Extension

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

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

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

Other U.S. Healthcare Laws and Compliance Requirements

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

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, recommending or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federally funded healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and/or formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. In addition, the statutory exceptions and regulatory safe harbors are subject to change.

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

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

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

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

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

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

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

Commercial distribution of products requires compliance with state laws that require the registration of manufacturers and wholesale distributors of drugs in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. In addition, several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. Certain local jurisdictions also require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Sales and marketing activities are also potentially subject to federal and state consumer protection and unfair competition laws.

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

Coverage, pricing and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the U.S. and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third party payors provide coverage, and establish adequate reimbursement levels for such products. In the U.S., third party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of its products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product, as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the U.S. Adequate third party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on its investment in product development.

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

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

U.S. Healthcare reform

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

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

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

The Foreign Corrupt Practices Act

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

Additional regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Europe / rest of world government regulation

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

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

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

Other regulations

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

Change in Fiscal Year

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

Human Capital Resources

As of April 30, 2025, we had a total of 270 full-time employees, of whom 171 were located in the U.S., 65 were located in the U.K., and 34 were located in the rest of the world. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages and consider our relations with employees to be good. We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees.

Corporate Information

Our principal executive offices are located at 55 Cambridge Parkway, Suite 901 East, Cambridge, MA 02142, and our telephone number is (857) 999-0075. Our website address is www.kalvista.com. The information contained on, or that can be accessed through, our website is not a part of this report. We have included our website address in this report solely as an inactive textual reference.

Available Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission ("SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are available on our corporate website at www.kalvista.com as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Also, the SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including us, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at www.sec.gov. The information posted on or accessible through these websites are not incorporated into this filing.

Item 1A.

Summary of Risk Factors

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

- We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.
- We may need substantial additional funding to allow us to support through clinical development and commercial launch, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- We are heavily dependent on the successful commercialization of EKTERLY (sebetralstat) and the development, regulatory approval, and commercialization of our current and future product candidates.
- We have not yet demonstrated an ability to successfully conduct commercial activities.
- We may fail to achieve the degree of market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success.
- The sales, marketing, and distribution of EKTERLY (sebetralstat) or any future approved products may be unsuccessful or less successful than anticipated. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market EKTERLY (sebetralstat) or any future approved products on acceptable terms, we may be unable to successfully commercialize EKTERLY (sebetralstat) or any future approved products.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- If we are unable to achieve and maintain third-party payor coverage and adequate levels of reimbursement for EKTERLY (sebetralstat) or any of our other product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.
- If serious adverse events or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit the development of some of our product candidates.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.
- Our operations and relationships with healthcare providers, healthcare organizations, customers and third- party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

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

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

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

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

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

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

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

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

- Shareholder activism could cause material disruption to our business.

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

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

Risk Factors

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

Risks Related to Our Business

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

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

- establish a commercial infrastructure to support the near-term commercialization of EKTERLY (sebetralstat) and any other product candidates for which we receive regulatory approval, including product sales, medical affairs, marketing, manufacturing and distribution;
- initiate the commercial launch of EKTERLY (sebetralstat) for the treatment of HAE in adult and pediatric patients aged 12 years and older;
- continue clinical development of sebetralstat in other indications as well as our current product candidates in our pipeline;
- seek to identify additional product candidates;
- acquire or in-license other products and technologies or enter into collaboration arrangements with regards to product discovery;
- initiate clinical trials for additional product candidates;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- maintain, expand and protect our intellectual property portfolio;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and

- continue to incur increased costs as a result of operating as a public company.

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

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

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

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

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

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

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

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

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

Risks Related to the Development and Commercialization of Our Product Candidates

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

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

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

- attracting, hiring and retaining qualified personnel.

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

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

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

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

We may fail to achieve the degree of market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success of EKTERLY (sebetralstat).

We received FDA approval for EKTERLY (sebetralstat) for the treatment of acute attacks of HAE in adult and pediatric patients aged 12 years and older in the U.S. on July 3, 2025. Nonetheless, we may fail to gain sufficient market acceptance by physicians, patients, third party payors and others in the medical community necessary for commercial success of EKTERLY (sebetralstat) in the U.S., any other jurisdictions that grant regulatory approval of sebetralstat for the treatment of HAE or any other product candidates. In addition, physicians, patients and third-party payors may prefer other products to ours. If sebetralstat and any other product candidates, if approved, do not achieve an adequate level of acceptance we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of sebetralstat and any other product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety and potential advantages and disadvantages compared to alternative treatments;
- the ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the clinical indications for which the product is approved
- changes in the standard of care for the targeted indications for the product;
- the strength of our marketing and distribution support;
- the price at which the product is offered for sale and the availability of third-party coverage and adequate reimbursement, including patient cost-sharing programs such as copays and deductibles;

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

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

In addition, in order to commercialize any product candidates, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize sebetralstat and any other product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing EKTERLY (sebetralstat) and any other product candidates that receive regulatory approval, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses. Our estimates of the potential market opportunities for our products and product candidates are informed by work that is not definitive and future analyses may lead to estimates that are higher or lower than these estimates than those provided at any given time, with respect to addressable patient populations. If our market opportunity is lower than anticipated, our business may suffer.

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

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

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

required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. For example, on April 8, 2025, we entered into the Kaken Agreement, pursuant to which we exclusively licensed commercialization rights to sebetralstat in Japan. If we are unable to enter into other such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval in additional indications or jurisdictions or any such commercialization may experience delays or limitations. In addition, we may have little or no control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. For example, if Kaken is unable to meet its contractual obligations pursuant to the Kaken Agreement, we may be forced to focus our efforts internally to commercialize sebetralstat in Japan, if approved, without the assistance of a commercialization partner or seek another commercialization partner, either of which would result in us incurring greater expenses and could cause a delay in market penetration while we expand our commercial operations or seek an alternative commercialization partner. Such costs may exceed the increased revenues we would receive from direct sebetralstat sales in Japan, at least in the near term. We would also potentially be forced to declare a breach of the agreement with Kaken and seek a termination of the agreement which could result in an extended and uncertain dispute with Kaken, including arbitration or litigation, any of which would be costly. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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

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

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches.

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

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

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

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

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

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

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

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain, and there is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the U.S., the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, if approved, as there is no body of established practices and precedents for these products.

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

Reimbursement agencies in Europe may be more conservative than CMS. Outside the U.S., international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the U.S. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, if approved. Accordingly, in markets outside the U.S., the reimbursement for our product candidates, if approved, may be reduced compared with the U.S. and may be insufficient to generate commercially reasonable revenues and profits.

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

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

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

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

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

The historical failure rate in clinical drug development of product candidates in our industry is high. Before obtaining regulatory approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of its product candidates in humans. Clinical testing is expensive, difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Further, the results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their products. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval.

We may experience delays in our clinical trials, including our ongoing KONFIDENT-KID and KONFIDENT-S trials of sebetralstat, and we do not know whether future clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. There can be no assurance that the FDA, MHRA, the EMA, or the Japanese Pharmaceuticals and Medical Devices Agency ("JPMDA") will not put any of our product candidates on clinical hold in the future. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA, MHRA, EMA, JPMDA or a comparable foreign regulatory authority on a trial design that we want to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical study;
- delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- inability, delay, or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- delay or failure in data collections in connection with a clinical trial;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical studies and increased expenses associated with the services of its CROs and other third parties;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- we may experience delays or difficulties in the enrollment of patients that our product candidates are designed to target;

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

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

- the cost of clinical trials of our product candidates may be greater than we anticipate;

- there may be political factors surrounding the approval process, such as government shutdowns or political instability;

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or

- there may be changes in governmental regulations or administrative actions.

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

- be delayed in obtaining regulatory approval for our product candidates;

- not obtain regulatory approval at all;

- obtain approval for indications, patient populations or doses that are not as broad as intended or desired;

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

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

- have the product removed from the market after obtaining regulatory approval.

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

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

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

Patient enrollment is affected by many factors including:

- the eligibility criteria for the study in question;

- the perceived risks and benefits of the product candidate under study;

- the efforts to facilitate timely enrollment in clinical trials;

- the inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same disease indication;

- the patient referral practices of physicians;

- the proximity and availability of clinical trial sites for prospective patients;

- ambiguous or negative interim results of our clinical trials, or results that are inconsistent with earlier results;

- feedback from the FDA, MHRA, EMA, JPMDA, or a comparable foreign regulatory authority or IRBs, data safety monitoring boards or results from earlier stage or concurrent preclinical and clinical studies, that might require modifications to the protocol;

- decisions by the FDA, MHRA, EMA, JPMDA, IRBs, a comparable foreign regulatory authority or us, or recommendations by data safety monitoring boards, to suspend or terminate clinical trials at any time for safety issues or for any other reason; and

- unacceptable risk-benefit profile or unforeseen safety issues or adverse effects.

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

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

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. For example, prior to FDA approval on July 3, 2025, on June 13, 2025, the FDA notified us that it would not meet the PDUFA goal date of June 17, 2025 for the regulatory approval of sebetralstat but indicated that it expected to deliver a decision within approximately four weeks. If we do not meet these milestones as publicly announced, or at all, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

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

We are not permitted to commercialize, market, promote or sell any product candidate in the U.S. without obtaining regulatory approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. If our product candidates are associated with undesirable effects in preclinical or clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Additional or more severe side effects may be identified for all our programs through further clinical studies or after regulatory approval is received. These or other drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may significantly harm our business, financial condition and prospects.

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

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

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

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

The process of obtaining regulatory approvals, both in the U.S. and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates and therapeutic indications involved. Failure to obtain regulatory approval for a product candidate will prevent us from commercializing the product candidate. Securing regulatory approval requires the submission of extensive chemistry, manufacturing and preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also usually requires inspection of manufacturing facilities by the regulatory authorities and also audits of the clinical trial sites, data and CROs that have supported KalVista in the clinical development. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining regulatory approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept an application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies.

Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application.

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

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

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

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

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

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

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

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

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information for or on behalf of a covered entity and their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

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

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

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

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

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. These risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

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

Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a disease with a prevalence of fewer than 200,000 individuals in the U.S., or if it affects more than 200,000 individuals in the U.S., there is no reasonable expectation that the cost of developing, and making the drug available in the U.S. for such disease will be recovered from sales of the drug.

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

The FDA granted orphan drug designation for EKTERLY (sebetralstat) on September 7, 2021. This designation may not effectively protect EKTERLY (sebetralstat) (or other drug products for which we may seek orphan designation) from competition because the designation does not preclude different drugs from being approved for the same condition. Even after an orphan designated drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that it is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

A fast track designation by the FDA may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive regulatory approval.

The FDA granted fast track designation for EKTERLY (sebetralstat) for the treatment of HAE and such designation was approved on July 3, 2025. We may also seek fast track designation for other indications of sebetralstat or for some of our other product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure that the FDA would decide to grant it. Even though we have received fast track designation for sebetralstat for the treatment of HAE, or even if we receive fast track designation for other indications or for our other product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Many drugs that have received fast track designation have failed to obtain drug approval.

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

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

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

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

The FDA, or other regulatory authorities, may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products and if we promote our products beyond their approved indications, we may be subject to enforcement action for off-label promotion. Violations of the FDC Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

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

- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;

- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of regulatory approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with U.S., U.K., E.U. and Japanese requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the requirements of the U.S., U.K., E.U. and Japan regarding the protection of personal information can also lead to significant penalties and sanctions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

Even if we choose to self-manufacture, the formulation used in early studies frequently is not a final formulation for commercialization. Additional changes may be required by the FDA or other regulatory authorities on specifications and storage conditions. These may require additional studies and may delay our clinical trials, including our ongoing KONFIDENT-KID and KONFIDENT-S trials.

We expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of EKTERLY (sebetralstat) and any other product candidates for which our collaborators or we obtain regulatory approval.

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

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

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

Third party manufacturers may not be able to comply with cGMP, regulations or similar regulatory requirements outside the U.S. If the FDA determines that our third-party manufacturers are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may not approve an NDA until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. Moreover, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our third-party manufacturers are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our third-party manufacturers, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

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

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

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

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

We may not successfully engage in strategic transactions, including any additional collaborations we seek, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expenses and present significant distractions to our management. The terms of any collaborations may also have impacts on other aspects of our business.

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

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

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks that would have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

In April 2025, we entered into the Kaken Agreement, pursuant to which we have licensed commercialization rights of sebetralstat in Japan, and we may enter into similar agreements in the future for additional geographies. In these and any future collaboration agreements, we expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of sebetralstat or any other product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We may not realize the full potential value of the Kaken Agreement or any future agreement.

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay our development program or one or more of our other development programs, delay our potential development schedule or reduce the scope of research activities, or increase our expenditures and undertake discovery or preclinical development activities at our own expense. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development activities, we may not be able to further develop our product candidates or continue to develop our product candidates and our business may be materially and adversely affected.

Our collaboration with Kaken and any future collaborations we may enter into may involve the following risks:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities;
- collaborators may delay discovery and preclinical development, provide insufficient funding for product development of targets selected by us, stop or abandon discovery and preclinical development for a product candidate, repeat or conduct new discovery and preclinical development for a product candidate;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than our products;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of its product candidates;
- collaborators may not properly maintain or defend their intellectual property rights or intellectual property rights licensed to us or may use their proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. For example, India and China do not allow patents for methods of treating the human body. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party has also filed a U.S. patent application prior to the effective date of the relevant provisions of the America Invents Act (i.e. before March 16, 2013) covering our products and product candidates, including EKTERLY (sebetralstat), or a similar invention, we may have to participate in an adversarial proceeding, known as an interference, declared by the USPTO to determine priority of invention in the U.S. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the E.U., the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

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

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

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

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

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

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

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringed their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure.

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

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

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

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

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

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

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

We are highly dependent on the research and development, clinical and business development expertise of the principal members of our management, scientific and clinical team. Although we have entered into employment letter agreements with our

executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of our management team, other key employees and other scientific and medical advisors, and our inability to find suitable replacements, could result in a failure to successfully commercialize EKTERLY (sebetralstat), delays in product development and harm our business.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery and preclinical development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to provide services to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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

We have grown from 150 employees as of April 30, 2024 to 270 employees as of April 30, 2025, and anticipate continuing to add headcount as we further develop our general and administrative capabilities. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

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

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

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

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

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

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

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

Our internal computer systems and those of our CROs, third-party manufacturers, collaborators and other third parties on whom we rely are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Furthermore, we have little or no control over the security measures and computer systems of our third party collaborators. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us or our CROs or other contractors or consultants we may utilize to mitigate network security problems, bugs, viruses, worms, cyberattacks, phishing attempts, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. For example, the loss of research data could delay development of our product candidates and the loss of clinical trial data from completed or ongoing or planned clinical trials, including our ongoing KONFIDENT-KID and KONFIDENT-S trials, could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our product candidates could be delayed or impaired.

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

- announcement of a strategic transaction or other significant events for us or our competitors;
- our decision to initiate a clinical trial or not to initiate a clinical trial;
- announcements of significant changes in our business or operations, including the decision not to pursue drug development programs;
- additions or departures of key personnel;
- adverse results or delays in clinical trials;
- changes in reimbursement or third party coverage of treatments, or changes to treatment recommendations or guidelines applicable to treatment;
- announcements relating to collaboration partnerships or other strategic transactions undertaken by us;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to EKTERLY (sebetralstat) or any of our other product candidates;
- any adverse changes to our relationship with any manufacturers or suppliers;
- the success of our testing and clinical trials;

- the success of our efforts to acquire or license or discover additional product candidates;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacture, supply or distribution shortages;
- actual or anticipated fluctuations in our operating results;
- FDA or other regulatory actions affecting us or our industry or other healthcare reform measures in the U.S., the U.K. or the E.U.;
- changes in financial estimates or recommendations by securities analysts;
- trading volume of our common stock;
- sales of our common stock by us, our executive officers and directors or our stockholders in the future;
- general economic and market conditions and overall fluctuations in the U.S. equity markets, including due to rising inflation and interest rates, labor shortages, supply chain issues, and global conflicts such as the war in Ukraine; and
- other events or factors, many of which are beyond our control.

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

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

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

We are subject to Section 404 of the Sarbanes-Oxley Act of 2002 ("Section 404"), and the related rules of the SEC which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. Effective April 27, 2020, the SEC adopted amendments to the "accelerated filer" and "large accelerated filer" definitions in Rule 12b-2 under the Securities and Exchange Act of 1934. The amendments exclude from the "accelerated filer" and "large accelerated filer" definitions an issuer that is eligible to be a smaller reporting company and that had annual revenues of less than $100 million in the most recent fiscal year for which audited financial statements are available. We determined that our Company does not meet the accelerated or large accelerated filer definitions as of April 30, 2025. For so long as we remain a smaller reporting company and a non-accelerated filer, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies, including, but not limited to, not being required as a non-accelerated filer to comply with the auditor attestation requirements of Section 404(b). An independent assessment by our independent registered public accounting firm of the effectiveness of internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

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

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

Shareholder Activism Could Cause Material Disruption to Our Business.

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

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

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

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;

- the required approval of at least 66 2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;

- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;

- the ability of our board of directors to alter our bylaws without obtaining stockholder approval;

- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal certain provisions of our bylaws and our amended and restated certificate of incorporation regarding the election and removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- the requirement that a special meeting of stockholders may be called only by or at the direction of our board of directors pursuant to a resolution adopted by a majority of the total number of directors that our board of directors would have if there were no vacancies, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and

- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us. In addition, these provisions would apply even if we were to receive an offer that some stockholders may consider beneficial.

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

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

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

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

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.

- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

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

Under the Tax Cuts and Jobs Act of 2017, ("TCJA"), net operating loss carryforwards ("NOLs") generated in taxable years beginning before January 1, 2018 may be carried forward up to twenty taxable years, and NOLs generated in taxable years beginning after December 31, 2017 will not expire, but will only be available to offset up to 80% of our taxable income in the taxable year (before taking into certain deductions). In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" (generally defined as a greater than 50-percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period) is subject to limitations on its ability to utilize its pre-change NOLs, to offset future taxable income. We have experienced ownership changes in the past that substantially limited our use of the NOLs available to us for U.S. federal income tax purposes and as a result we currently expect that approximately $76.7 million of our NOLs will go unutilized. If we undergo additional ownership changes (some of which changes may be outside our control), our ability to utilize our NOLs could be further limited by Section 382 of the Code. Our NOLs may also be impaired under state law and there may be periods in which certain states suspend our ability to use our NOLs. Accordingly, we may not be able to utilize a material portion of our NOLs against future taxable income. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. federal taxable income. We have incurred net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our NOLs.

General Risk Factors

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

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

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

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

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

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management & Strategy:

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

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

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

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

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

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

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

Governance:

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

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

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

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

Item 2. Properties.

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

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

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

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not Applicable.

PART II

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

Market Information

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

Holders

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

Dividends

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

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. Reserved.

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

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

Management Overview

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

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

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

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

Key Updates

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

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

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

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

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

Change in fiscal year

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

Financial Overview

Revenue

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

Research and Development Expenses

Research and development expenses primarily consist of costs associated with our research activities, including the cost to manufacture the commercial drug supply of EKTERLY (sebetralstat) prior to any FDA approval and preclinical and clinical development of product candidates. We contract with clinical research organizations to manage our clinical trials under agreed upon budgets for each study, with oversight by our clinical program managers. All research and development costs are expensed as incurred.

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

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

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

General and Administrative Expenses

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

Other Income

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

Income Taxes

We historically have incurred net losses and have had no corporation tax liabilities. We file U.S. Federal tax returns, as well as certain state returns. We also file returns in the United Kingdom. Under the U.K. government's research and development tax incentive scheme, we have incurred qualifying research and development expenses and filed claims for research and development tax credits in accordance with the relevant tax legislation. The research and development tax credits are paid out to us in cash and reported as other income. For tax purposes, we capitalize and subsequently amortize all allowable R&D expenditures over five years for research activities conducted in the U.S. and over fifteen years for research activities conducted outside of the U.S. As a result of the November 2024 PSA and the Kaken Agreement executed in April 2025, the $100.0 million up-front payment and the $11.0 million up-front payment, respectively, were treated as income for tax purposes in the UK under the Research and Development Expenditure Credit scheme. After applying the estimated net operating loss carryforwards and research and development tax credits, we recorded income tax expense of $3.4 million for the year ended April 30, 2025.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the U.S. ("U.S. GAAP"). The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of our financial statements and the reported revenue and expenses during the reported periods. We evaluate these estimates and judgments, including those described below, on an ongoing basis. We base our estimates on historical experience, known trends and events, contractual milestones and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. See also Note 2, Summary of Significant Accounting Policies to our

Consolidated Financial Statements included in this Annual Report on Form 10-K, which discusses the significant assumptions used in applying our accounting policies. Those accounting policies and estimates that we deem to be critical are as follows:

Liability Related to the Deferred Royalty Obligation

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

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

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

Results of Operations

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

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

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

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

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

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

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

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

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

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

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

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

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

Liquidity and Capital Resources

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

Sources of Liquidity

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

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

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

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

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

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

Cash Flows

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

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

Net cash used in operating activities

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

Net cash (used in) provided by investing activities

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

Net cash provided by financing activities

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

Recent Accounting Pronouncements

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

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

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

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed are listed in Item 15 of this Annual Report on Form 10-K and incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Exchange Act of 1934, our management, under the supervision and with the participation of our Chief Executive Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of April 30, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of April 30, 2025 our Chief Executive Officer has concluded that, as of April 30, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

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

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

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

Our management, with the participation of our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of April 30, 2025. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 *Internal Control – Integrated Framework*. Based on our assessment, our management has concluded that, as of April 30, 2025, our internal control over financial reporting is effective based on those criteria.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Effective April 27, 2020, the SEC adopted amendments to the "accelerated filer" and "large accelerated filer" definitions in Rule 12b-2 under the Exchange Act. The amendments exclude from the accelerated and large accelerated filer definitions an issuer that is eligible to be a smaller reporting company and that had annual revenues of less than $100 million in the most recent fiscal year for which audited financial statements are available. We determined that our Company does not meet the accelerated or large accelerated filer definitions as of April 30, 2025. For as long as we remain a non-accelerated filer, we intend to take advantage of the exemption permitting us not to comply with the requirement under Section 404(b) of the Sarbanes-Oxley Act of 2002 that our independent registered public accounting firm provide an attestation on the management's assessment of the effectiveness of our internal control over financial reporting.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the year ended April 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Insider Trading Arrangements and Policies

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

ATM

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

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

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

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

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

Item 9C. Disclosure Regarding Jurisdictions That Prevent Inspections

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

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

Item 11. Executive Compensation.

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

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

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

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

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

Item 14. Principal Accounting Fees and Services.

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

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K:

(1) *Consolidated Financial Statements.* See Index to Financial Statements beginning on page F-1 of this Annual Report, which are incorporated by reference.

(2) *Financial Statement Schedules.* All schedules have been omitted because the information required to be presented in them is not applicable or is shown in the financial statements or related notes.

(3) *Exhibits.* We have filed, or incorporated into this Annual Report on Form 10-K by reference, the exhibits listed on the accompanying Exhibit Index.

(b) *Exhibits.*

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

	by and between KalVista. Pharmaceuticals Ltd and Dr. Christopher M. Yea.					
10.14#	Amended and Restated Executive Employment Agreement between Registrant and Paul K. Audhya, dated September 9, 2024.	8-K	001-36830	10.3	September 10, 2024	
10.15	First Amendment of Lease, dated November 20, 2020, to the Office Lease Agreement by and between the Registrant and 55 Cambridge Parkway, LLC, dated May 19, 2017.	10-Q	001-36830	10.1	December 10, 2020	
10.16#	Amended and Restated Executive Employment Agreement between the Registrant and Benjamin L. Palleiko, dated September 9, 2024.	8-K	001-36830	10.2	September 10, 2024	
10.17	Amended and Restated 2021 Equity Inducement Plan and forms of agreement.	S-8	333-280579	99.1	June 28, 2024	
10.18	Separation Agreement by and between the Registrant and T. Andrew Crockett, dated March 6, 2024.	10-Q	001-36830	10.2	September 5, 2024	
10.19#	Executive Employment Agreement by and between the Registrant and Brian Piekos, dated September 9, 2024.	8-K	001-36830	10.1	September 10, 2024	
10.20	Securities Purchase Agreement by and between KalVista Pharmaceuticals, Inc. and DRI Healthcare Acquisitions LP, dated November 4, 2024.	8-K	001-36830	1.2	November 4, 2024	
10.21	Purchase and Sale Agreement by and among the Registrant, as guarantor, KalVista Pharmaceuticals Ltd. and DRI Healthcare Acquisitions LP, dated November 4, 2024.	10-Q	001-36830	10.1	March 12, 2025	
10.22	Debenture by and between KalVista Pharmaceuticals Ltd and DRI Healthcare Acquisitions LP, dated November 4, 2024.	10-Q	001-36830	10.2	March 12, 2025	
10.23	License, Supply, and Distribution Agreement between Kaken Pharmaceutical Co., Ltd and KalVista Pharmaceuticals, Ltd, dated April 8, 2025.					X
10.24	Sales Agreement between the Company and TD Securities (USA) LLC, dated July 10, 2025.					X
19.1	Insider Trading Policy.					X
21.1	Subsidiaries of the Registrant.					X
23.1	Consent of Deloitte & Touche LLP.					X
24.1	Power of Attorney. (See signature page hereto.)					X
31.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as					X

	adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					
32.2*	Certification of Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
97.1	Compensation Recovery Policy	10-K	001-36830	97.1	July 11, 2024	
101.INS	Inline XBRL Instance Document - the instance document does not appear in the interactive data file because its XBRL tags are embedded within the inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					X

Management contract or compensatory plan or arrangement.

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

^ Registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

KalVista Pharmaceuticals, Inc.

Date: July 10, 2025

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

POWER OF ATTORNEY

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

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

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

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KALVISTA PHARMACEUTICALS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of KalVista Pharmaceuticals, Inc. and subsidiaries (the "Company") as of April 30, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows, for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of April 30, 2025 and 2024, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matter

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

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

Critical Audit Matter Description

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

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

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

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

How the Critical Audit Matter Was Addressed in the Audit

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

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

/s/ Deloitte & Touche LLP

Boston, Massachusetts
July 10, 2025

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

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

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

See notes to consolidated financial statements.

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

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

See notes to consolidated financial statements.

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

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

See notes to consolidated financial statements.

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

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

See notes to consolidated financial statements.

Note 1. Description of Business and Basis of Presentation

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

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

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

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

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

Change in fiscal year

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

Note 2. Summary of Significant Accounting Policies

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

Segment Reporting: The chief operating decision maker, the CEO, manages the Company's operations as a single operating segment for the purposes of assessing performance and making operating decisions, and as such, the Company has one operating segment. Refer to Note 15, *Segment Information*, for further information.

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

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

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

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

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

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

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

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

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

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

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

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

Asset Classification	Estimated Useful Life
Machinery and equipment	1-5 Years
Furniture and fixtures	1-5 Years
Computer equipment	3-4 Years
Leasehold improvements	15 Years or term of lease, if shorter

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Employee-related expenses including salaries, benefits, travel, and share-based compensation expense for research and development personnel;
- Costs to manufacture the commercial drug supply of EKTERLY prior to FDA approval;
- Costs associated with preclinical and development activities;
- Costs associated with regulatory operations.

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

Income taxes: The Company accounts for income taxes using an asset and liability approach. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The Company evaluates the realizability of its deferred tax assets and establishes a valuation allowance when it is more likely than not that all or a portion of deferred tax assets will not be realized. The Company has provided a full valuation allowance on its deferred tax assets.

Relative to accounting for uncertainties in tax positions, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. For those tax positions where it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, the Company does not recognize a tax benefit in the financial statements.

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

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

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

Potential dilutive common share equivalents consist of:

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

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

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

Fair value measurement: The Company classifies fair value measurements using a three-level hierarchy that prioritizes the inputs used to measure fair value. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 - Quoted market prices in active markets for identical assets or liabilities;
- Level 2 - Observable inputs other than quoted market prices included in Level 1, such as quoted market prices for markets that are not active or other inputs that are observable or can be corroborated by observable market data;
- Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

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

Note 3. Fair Value Measurements

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

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

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

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

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

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

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

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

Marketable Securities

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

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

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

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

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

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

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

Note 4. Prepaid Expenses and Other Current Assets

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

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

Note 5. Property and Equipment

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

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

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

Note 6. Accrued Expenses

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

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

Note 7. Stockholder's Equity

Direct Offerings

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

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

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

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

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

Note 8. Stock-Based Compensation

The Company has four plans that provide for equity-based compensation. Two are legacy plans for which no further grants are to be made. As of April 30, 2025, 1,466,813 stock awards remain available for grant under the 2017 Equity Incentive Plan ("2017 Plan"). There are 8,916,060 shares of the Company's common stock that are reserved for issuance upon exercise or settlement of stock options or other awards under these four plans. Initial awards generally vest 25% after one year and then ratably on a monthly basis over the next three years. Recurring grants typically vest on a monthly basis over four years. Stock option grants expire after ten years.

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

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

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

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

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

	2025	2024
Risk-free interest rate	4.21%	4.29%
Expected life of the options	6.25 years	6.25 years
Expected volatility of the underlying stock	79.85%	81.38%
Expected dividend rate	0%	0%

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

	Year ended April 30, 2025	2024
Research and development	$ 4,959	$ 9,305
General and administrative	7,332	12,610
Total stock-based compensation expense	$ 12,291	$ 21,915

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

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

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

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

Restricted Stock Units

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

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

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

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

Performance Stock Units

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

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

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

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

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

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

Note 9. Commitments and Contingencies

Commitments

Clinical Studies: The Company enters into contractual agreements with contract research organizations in connection with preclinical and toxicology studies and clinical trials. Amounts due under these agreements are invoiced to the Company on predetermined schedules during the course of the studies and clinical trials and are not refundable regardless of the outcome. The Company has a contractual obligation related to the expected future costs to be incurred to complete the ongoing preclinical studies and clinical trials. The remaining clinical commitments, which have cancellation provisions, totaled $18.1 million as of April 30, 2025.

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

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. There were no contingent liabilities requiring accrual at April 30, 2025 and 2024.

Indemnification

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

Note 10. Leases

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

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

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

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

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

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

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

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

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

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

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

Note 11. Purchase and Sale Agreement

Royalty Liability

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

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

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

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

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

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

Embedded Derivative Liability

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

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

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

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

Note 12: License, Supply and Distribution Agreement

Kaken Pharmaceutical Co., Ltd.

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

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

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

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

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

Note 13. Income Taxes

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

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

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

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

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

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

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

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

The ability to utilize the Company's domestic net operating losses is limited due to changes in ownership as defined by Section 382 of the Internal Revenue Code (the "Code"). Under the provisions of Sections 382 and 383 of the Code, a change of control, as defined in the Code, imposes an annual limitation on the amount of the Company's pre-change net operating loss and tax credit carryforwards, and other tax attributes that can be used to reduce future tax liabilities. The Company determined that ownership changes occurred as a result of public offerings in December 2005, a transaction in November 2016, and public offerings in February 2019 and December 2022. The Company most recently underwent a change of ownership on December 28, 2022. The Company evaluated the 382 position for the period of December 29, 2022 through April 30, 2025 and concluded that the Company did not have any ownership changes during the period of December 29, 2022 to April 30, 2025.

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

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

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

The Company recognizes the financial statement effects of a tax position when it becomes more likely than not, based upon the technical merits, that the position will be sustained upon examination. The Company files U.S. Federal tax returns, as well as certain state returns. The Company also files returns in the United Kingdom. The Company is subject to U.S. Federal, state, and U.K. income tax examinations by authorities for tax years ending after 2021. There are currently no federal, state, or U.K. audits in process. Tax year 2021 and subsequent years contain matters that could be subject to differing interpretations of the applicable tax laws and regulations as it relates to the amount and or timing of income, deductions, and tax credits. Although the outcome of tax audits is always uncertain, management has analyzed the Company's tax positions taken for all open tax years and has concluded that no provision for unrecognized tax benefits from uncertain tax positions is required in the Company's consolidated financial statements for the years ended April 30, 2025 and 2024, respectively.

Under the U.K. government's research and development tax incentive scheme, we have incurred qualifying research and development expenses and filed claims for research and development tax credits in accordance with the relevant tax legislation. The research and development tax credits are paid out to us in cash and reported as other income. As a result of the November 2024 PSA and the Kaken Agreement executed in April 2025, the $100.0 million up-front payment and the $11.0 million up-front payment, respectively, were treated as income for tax purposes in the UK under the Research and Development Expenditure Credit scheme. After applying the estimated net operating loss carryforwards and research and development tax credits, we recorded income tax expense of $3.4 million for the year ended April 30, 2025 due to an increase in the valuation allowance against our deferred tax assets.

Note 14. Defined Contribution Plans

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

Note 15: Segment Information

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

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

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

Note 16. Other Income (Expenses), Net

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

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

As of April 30, 2025 and 2024 the Company had research and development tax credits receivable totaling $1.4 million and $8.4 million, respectively. This tax credit is related to a tax scheme for small and medium enterprises in the U.K. as well as an R&D expenditure credit system that allows the Company to file a claim for cash credit in proportion to the Company's R&D expenditure for the year. This amount is included in other income, as it is a refundable credit that does not depend on the Company's ongoing tax status or position. The Company recognized $5.0 million and $8.5 million related to these programs in the years ended April 30, 2025 and 2024, respectively.

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

Note 17. Subsequent Events

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

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

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