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 December 31, 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: 001-43047

Aktis Oncology, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**85-2584233**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
17 Drydock Avenue, Suite 17-401 Boston, Massachusetts	**02210**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 461-4023

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	AKTS	The Nasdaq Stock Market LLC

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

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

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

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

Indicate by check mark whether the Registrant has submitted electronically 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 definitions 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 recovery 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 Registrant did not have a public float on the last business day of its most recently completed second fiscal quarter because there was no public market for the Registrant's common equity as of such date.

The number of shares of Registrant's Common Stock and Class A common stock outstanding as of March 10, 2026 was 53,403,173 and 1,872,829, respectively.

DOCUMENTS INCORPORATED BY REFERENCE

None.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Forward-looking statements are neither historical facts nor assurances of future performance. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "estimate," "believe," "predict," "potential" or "continue" or the negative of these terms or other similar expressions intended to identify statements about the future, although not all forward-looking statements contain these identifying words. These forward-looking statements include, without limitation, statements about the following:

- the timing, scope, progress and results of our research and development programs, preclinical studies, clinical trials, investigational new drug or biological license applications, and other regulatory submissions;
- the timing of, and costs involved in, obtaining and maintaining regulatory approval of [^{225}Ac]Ac-AKY-1189 for Nectin-4 expressing tumors, [^{225}Ac]Ac-AKY-2519 for B7-H3 expressing tumors and any other current or future product candidates that we may identify or develop;
- our ability to obtain an adequate supply at reasonable costs of ^{225}Ac or any other radioisotope we may incorporate into our drug candidates;
- our ability to address the fulfillment and logistical challenges posed by the time-limited stabilization of [^{225}Ac]Ac-AKY-1189 for UC and other Nectin-4 expressing tumors or any other current or future product candidate we develop;
- our ability to obtain funding for our operations necessary to complete the clinical trials for [^{225}Ac]Ac-AKY-1189 for Nectin-4 expressing tumors, our other product candidates, or any future product candidates;
- our ability to identify patients with the diseases treated by our product candidates, and to enroll patients in trials;
- our expectations regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of our product candidates, if approved for commercial use;
- our ability to advance our miniprotein radioconjugate platform;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements, including our ability to comply with our financial obligations pursuant to the terms of such agreements;
- the timing and likelihood of the achievement of milestones pursuant to our existing collaboration and licensing agreements;
- our ability to identify and develop product candidates for treatment of additional indications;
- our commercialization, marketing and manufacturing capabilities and strategy, including the timing and costs of constructing our own current Good Manufacturing Practices facility;
- the performance of our third-party service providers, including our suppliers and manufacturers;
- the rate and degree of market acceptance and clinical utility for, [^{225}Ac]Ac-AKY-1189 for UC and any other Nectin-4 expressing tumors, and any other current or future product candidates we may develop;
- the effects of competition with respect to [^{225}Ac]Ac-AKY-1189, any other current or future product candidates, as well as innovations by current and future competitors in our industry;
- the implementation of our strategic plans for our business, any product candidates we may develop;
- our estimates regarding the market opportunities for our drug candidates;
- our intellectual property position, including the scope of protection we are able to establish, maintain, defend, protect and enforce for intellectual property rights covering our product candidates;
- our ability to attract and retain key scientific or management personnel;
- regulatory and legal developments in the United States and foreign countries;
- our expectations regarding the period during which we qualify as an emerging growth company and smaller reporting Company under the Jumpstart Our Business Startups Act of 2012, as amended;
- business disruptions affecting the initiation, patient enrollment, development and operation of our clinical trials, including a public health emergency, such as the recent global COVID-19 pandemic;

- the accuracy of our estimates regarding future expenses, future revenue, capital requirements and need for additional financing; and
- our financial performance and our ability to effectively manage our anticipated growth.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein for any reason after the date of this report to conform these statements to new information, future events or otherwise.

You should read this Annual Report on Form 10-K and the documents that we reference herein and have filed with the SEC as exhibits to this Annual Report on Form 10-K with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

SUMMARY RISK FACTORS

The risk factors summarized and detailed below could materially harm our business, operating results and/or financial condition, impair our future prospects and/or cause the price of our common stock to decline. These are not all of the risks we face, and other factors not presently known to us or that we currently believe are immaterial may also affect our business if they occur. A summary of the material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

- We have incurred significant losses since our inception, have no products approved for sale, and we expect to incur losses for the foreseeable future.
- Our limited operating history may make it difficult for you to evaluate our prospects and likelihood of success.
- We will require additional funding to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we would be forced to delay, reduce, or eliminate our research and product candidate development programs.
- We are early in our development efforts. If we are unable to develop, and commercialize, any of our current or future product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.
- Our business is highly dependent on our lead product candidate, [^{225}Ac]Ac-AKY-1189, for the treatment of Nectin-4 expressing tumors. We must complete clinical trials before we can seek regulatory approval and begin commercialization of [^{225}Ac]Ac-AKY-1189. If we are unable to obtain regulatory approval for, and successfully commercialize, [^{225}Ac]Ac-AKY-1189, our business may be materially harmed, and such failure may affect our other current or future product candidates.
- Preclinical and clinical development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If preclinical studies or clinical trials of a product candidate are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize [^{225}Ac]Ac-AKY-1189 for any indication or any of our other current or future product candidates on a timely basis or at all.
- Our approach to the discovery and development of product candidates using our miniprotein radioconjugate platform represents a novel approach to radiation therapy, which may create significant and potentially unpredictable challenges for us.
- Our product candidates may cause adverse events, undesirable side effects or have other properties that could halt their preclinical or clinical development, prevent, delay, or cause the withdrawal of their regulatory approval, limit their commercial potential, or result in significant negative consequences, including death of patients.
- Results of preclinical studies, dosimetry assessments, and early-stage clinical trials may not be predictive of the results of future preclinical studies or clinical trials.
- Interim, topline, or preliminary data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more patient data becomes available or as we make changes to our manufacturing processes and are subject to audit and verification procedures that could result in material changes in the final data.
- The commercial success of [^{225}Ac]Ac-AKY-1189, or any of our other current or future products, if approved, will depend upon public perception of radiopharmaceuticals and the degree of their market acceptance by physicians, patients, healthcare payors and others in the medical community. Even if [^{225}Ac]Ac-AKY-1189, or any other product

candidates we develop receive marketing approval by the FDA or other foreign regulatory authority, they may not achieve the level of commercial acceptance and sales experienced by approved beta-emitting therapies, Pluvicto and Lutathera.

- We face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.
- The development and commercialization of pharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for [^{225}Ac]Ac-AKY-1189 or our other current or future product candidates, on a timely basis if at all, our business will be substantially harmed.
- We intend to build and operate our own manufacturing facility for preclinical and clinical supply needs, which will require significant resources, and we may fail to successfully establish and operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.
- Our product candidates are biologics and the manufacture of our product candidates is complex. Even after our planned manufacturing facility is operating, we will continue to rely on third parties to manufacture our product candidates. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product supplies or product candidates, or fail to do so at acceptable quality levels or prices.
- We may be unable to obtain a sufficient supply of ^{225}Ac or other radioisotopes to support clinical development or manufacturing at commercial scale.
- We will rely on third parties to conduct our Phase 1b clinical trial of [^{225}Ac]Ac-AKY-1189 and plan to rely on third parties to conduct future clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.
- We do not own or expect to own any issued patents relating to the radioactive payload, ^{225}Ac, used in our product candidates, including [^{225}Ac]Ac-AKY-1189 and [^{225}Ac]Ac-AKY-2519.
- Our success depends on our ability to obtain, maintain, enforce, defend and protect our intellectual property and our proprietary technologies, and conduct our business without infringing, misappropriating or otherwise violating intellectual property or proprietary rights of others.
- Our stock price may be volatile or may decline regardless of our operating performance, resulting in substantial losses for investors.

Table of Contents

PART I

Item 1. Business.

Overview

We are a clinical-stage oncology company focused on expanding the breakthrough potential of targeted radiopharmaceuticals to large patient populations, including those not addressed by existing platform technologies. The field of targeted radiopharmaceuticals is currently led by two marketed products that illustrated transformative survival outcomes and quality of life benefits can be conferred by delivering radioisotopes to solid tumors. These leading products, which target prostate specific membrane antigen or somatostatin-2 receptor, are each currently approved in only one tumor type, yet have seen considerable commercial uptake and have become fundamental pillars of cancer treatment. Despite these advances, we believe that the field of radiopharmaceuticals is still in its infancy, with many emerging companies still primarily focused on these same two targets. In contrast, we see a significant opportunity to broaden the cancer patient populations benefiting from targeted radiopharmaceuticals by developing next-generation technologies that expand the scope of tumor targets for which it is possible to safely deliver a powerful payload of an alpha-emitting radioisotope. To ensure patient demand is reliably met, we are also establishing efficient end-to-end supply, with a combination of critical internal capabilities paired with established external vendors. Through these efforts, we seek to maximize clinical utility across multiple indications in multiple tumor types, and to expand the commercial uptake of radiopharmaceuticals beyond the traditional nuclear medicine setting and into the more expansive clinical oncology setting.

We have built a proprietary miniprotein radioconjugate platform that aims to safely confer breakthrough efficacy to a broad range of patient populations. Our miniprotein radioconjugates are designed to selectively deliver the tumor-killing properties of radioisotopes to targeted tumors with high tumor penetration and prolonged tumor retention, while being rapidly cleared from normal organs and tissues to minimize systemic radiation exposure. Our miniproteins have demonstrated the ability to potently bind to tumor targets outside the scope of current delivery technologies such as peptide-based radioconjugates. We are leveraging the capabilities of our platform technology, together with our expertise and know-how in radiopharmaceutical development, supply chain and manufacturing, to address these challenges with the aim of advancing a deep pipeline of programs against a broad range of tumor targets that have not been successfully targeted with radiopharmaceuticals.

Our platform capabilities have generated a pipeline of several novel product candidates. Our most advanced program is a radiopharmaceutical targeting Nectin-4. It is a miniprotein radioconjugate with multi-indication potential across multiple tumor types, in clinical development for the treatment of locally advanced or metastatic urothelial cancer, or UC, and multiple other Nectin-4 expressing solid tumor types. The learnings from the optimization of our Nectin-4 program, the first miniprotein radioconjugate ever advanced into human investigational studies, are being applied to benefit the development of our robust pipeline of several other unpartnered miniprotein radioconjugate programs, which are designed to address other clinically-validated targets.

Our lead product candidate, [^{225}Ac]Ac-AKY-1189, contains a miniprotein, AKY-1189, that specifically binds to Nectin-4, and is conjugated via chelation to actinium-225, ^{225}Ac. ^{225}Ac, is an alpha-emitting radioisotope that when conjugated to a prostate specific membrane antigen, or PSMA, binding peptide has been shown to confer increased anticancer activity in the post-chemotherapy setting of metastatic castration-resistant prostate cancer compared to an identical PSMA binding peptide with beta-emitting Lutetium-177, or ^{177}Lu. Nectin-4 is a surface protein found on a wide variety of tumors and has very limited expression in normal adult tissues. Nectin-4 is also the target of Padcev, an antibody-drug conjugate, or ADC, approved worldwide for the treatment of locally advanced or metastatic UC. Padcev has an annualized treatment cost of approximately $500,000 and had worldwide sales of $1.9 billion in 2024, with estimated peak sales of up to $7.0 billion.

Despite the commercial success of Padcev, its impact beyond UC has been limited likely due to the need to develop a companion diagnostic for tissue testing when utilizing an ADC. In contrast, we intend to use imaging radioisotopes conjugated to AKY-1189 to select patients most likely to benefit from therapeutic treatment with [^{225}Ac]Ac-AKY-1189. We believe the commercial impact of Padcev validates Nectin-4 as an anticancer target in UC and that significant unmet medical need exists for our lead product candidate in post-Padcev UC. Additionally, we see potential to treat several non-UC Nectin-4-expressing tumor types such as breast cancers and lung cancers. We believe that the therapeutic potential of [^{225}Ac]Ac-AKY-1189 across multiple tumor types is supported by our preclinical studies and data collected by a third-party physician in South Africa pursuant to Section 21 of the Medicines and Related Substances Act, or MRSA, which demonstrated the ability of radiolabeled AKY-1189 to specifically localize to Nectin-4 expressing tumors and rapidly clear from normal organs and tissues. In April 2025, the U.S. Food and Drug Administration, or the FDA, cleared our investigational new drug, or IND, application for [^{225}Ac]Ac-AKY-1189 for the treatment of locally advanced or metastatic UC and other Nectin-4 expressing tumors. We have commenced a multi-site Phase 1b clinical trial in the United States and anticipate preliminary results from the Part-1 dose escalation portion of this trial in the first quarter of 2027.

To overcome the manufacturing challenges and supply chain reliability issues that have historically hindered the development and commercialization of radiopharmaceuticals, we are focused on investing in manufacturing and ensuring supply chain continuity and reliability. We have built significant internal capabilities, including subject matter expertise for our product manufacturing processes and a state-of-the-art radiopharmaceutical development suite. Additionally, we have partnered with multiple domestic and international isotope suppliers that provides us priority access to ^{225}Ac, and with multiple contract manufacturers for the production of our drug product, which collectively are designed to create redundancies across all components of our supply chain. We are also establishing our own current good manufacturing practice, or cGMP, facility to enhance flexibility, increase control, and establish a hybrid internal and external clinical supply chain. We believe our team's expertise and experience in the development of radiopharmaceuticals will allow us to address the challenges presented by the half-life of radioactive isotopes and establish an efficient supply chain from production to patient administration.

We believe that radiopharmaceuticals represent one of the most promising modalities for the treatment of solid tumors. Approved radiopharmaceuticals have demonstrated the ability to overcome the challenges of conventional cancer treatments and provide patients with targeted therapies that have superior efficacy and better tolerability. We believe our approach is validated by, and builds upon, the clinical and commercial success of current radiopharmaceuticals and that our approach has the potential to further transform the cancer treatment paradigm for large patient populations.

- *Clinical validation of targeted radiopharmaceuticals.* Approved beta-emitting radiopharmaceuticals, Pluvicto and Lutathera, have demonstrated statistically significant and clinically meaningful overall survival, progression-free survival and quality of life benefits in global registrational clinical trials. Early-stage clinical trials have also demonstrated that the use of alpha-emitting ^{225}Ac radioconjugates can deliver more profound anticancer activity than beta-emitting ^{177}Lu conjugates in similar patient populations, and in patients whose disease has progressed on prior beta-emitting targeted therapies. These promising early clinical data have led to the advancement of ^{225}Ac-based radioconjugates to pivotal clinical trials, though none yet have filed for approval by the FDA.
- *Commercial validation of approved radiopharmaceuticals.* Pluvicto achieved a first full year of sales of approximately $1 billion, with an annualized treatment cost of approximately $300,000, representing the strongest oncology commercial launch since Ibrance in 2015, which demonstrates the patient impact potential and rapid adoption of radiopharmaceuticals into clinical practice. The estimated global peak sales for Pluvicto are approximately $5.4 billion in prostate cancer alone. The global radiopharmaceuticals market is one of the fastest growing categories among anticancer medicines, and is projected to grow to over $26 billion in sales by 2032. The therapeutic segment of this market is estimated to achieve a total addressable market of $25 billion to $60 billion post-2030.
- *Strategic validation of radiopharmaceuticals.* The commercial success of radiopharmaceuticals, paired with significant increases in investment in innovative approaches, has led to significant value creation through partnering and acquisitions. Aggregate transaction values over the last 10 years are approximately $33 billion. Several large multinational biopharmaceutical oncology leaders have also been significantly investing in radiopharmaceutical operations globally. We believe that the continued capital investment and expansion of operations and the advancement of supply chain capabilities represent recognition of the significant medical and commercial opportunity for radiopharmaceuticals.

Our proprietary miniprotein radioconjugate platform

We created our proprietary miniprotein radioconjugate platform to build on the successes of currently available radiopharmaceuticals and enable the discovery of next-generation precision radiopharmaceuticals. We are leveraging our platform to discover and develop radiopharmaceutical therapies that selectively deliver the tumor-killing properties of radioisotopes to targeted tumors with high tumor penetration and prolonged retention, with the goal of enhancing the safety and tolerability profile by rapidly clearing from normal organs and tissues to minimize systemic radiation exposure. Our miniprotein radioconjugates are designed for use with either imaging isotopes to select patients expressing the target, or therapeutic isotopes to treat tumors. The radioconjugates are formed by a chelation reaction to bind the isotopes to DOTA, which is covalently linked to the tumor-targeting miniprotein. This approach will enable clinicians to first visualize and verify target tumor engagement using an imaging radioisotope, thereby identifying the patients who are most likely to benefit from our therapy.

Our platform has enabled us to engineer potent, precision miniprotein-based radioconjugates that bind to the surface targets on tumor cells to localize radioisotope payloads. Miniproteins are polypeptides of less than one hundred amino acids that are amenable to biologic and medicinal chemistry optimization methods. We are prioritizing miniprotein binders of 40 to 70 amino acids in length, which are classified as biologics from a regulatory perspective providing a twelve-year exclusivity period for approved products. Miniproteins have differentiated and highly attractive properties as radioconjugates based on their antibody-like ability to potently and selectively bind to a highly diverse set of tumor targets, while having the pharmacologic profile of small peptides to enable high tumor penetration and rapid clearance from the body. We believe that miniproteins have many of the advantages of larger biologics like antibodies, as well as advantages of the smallest binders like peptides, without the limitations specific to either

class. In particular, based on our preclinical studies, we believe miniproteins have the following beneficial characteristics for use in radiopharmaceuticals:

- *Enhanced anticancer activity.* Tumor killing is achieved through delivery of absorbed radiation dose, which is enhanced by high tumor penetration, high binding affinity for tumor targets, and prolonged retention of drug in the tumor.
  - *Improved tumor penetration as compared to larger biologics.* Due to their small diameters, miniproteins can achieve high tumor penetration. In contrast, antibodies are unable to rapidly penetrate tumors to the same extent due to their much larger size.
  - *High affinity for tumor targets.* Increased affinity is associated with higher tumor uptake. We have reproducibly generated sub-nanomolar affinity miniprotein binders to specific tumor targets.
  - *Internalization into tumor cells and prolonged tumor retention*. Our miniprotein radioconjugates are internalized into cancer cells, which we believe drives prolonged retention time in tumors. In a clinical imaging assessment, AKY-1189 was measured for two days following administration and robust tumor retention was observed through the duration of the assessment. In preclinical studies in animals with significantly faster plasma clearance than humans, we measured out to three days following administration and observed robust retention of AKY-1189 in the tumor for the duration of the study.
- *Enhanced clearance, selectivity and kidney exposure.*
  - *Rapid clearance from the body to minimize toxicities.* The most common dose-limiting toxicity for targeted radiopharmaceuticals is hematologic and bone marrow toxicity. To lower the risk of radiation exposure to bone marrow, we have designed our product candidates to have a short plasma half-life in order to be rapidly cleared through the kidney. Rapid clearance of the radioisotope payload from the body minimizes the exposure to radiation of normal organs and tissues, such as the blood, bone marrow and skin. Unlike antibodies or other large biologic radioconjugates that take days to weeks to be eliminated from circulation, miniproteins are typically eliminated from circulation within hours, thereby minimizing systemic exposure and potentially increasing the therapeutic index of our miniproteins relative to other radiopharmaceutical constructs.
  - *High selectivity.* Miniproteins, like antibodies, can target specific isoforms or variants of closely related protein targets and differentiate among them, resulting in higher selectivity as compared to peptides. Our product candidates have demonstrated high selectivity for their tumor targets using a well-established cell-surface array assay. We believe this selectivity will reduce the risk of off-target binding and radioactive exposure to normal organs and tissues.
  - *Reduced kidney exposure through molecular engineering.* The kidney is not only the organ that clears miniproteins from the body but it also plays the physiologic role in reabsorbing renally-cleared peptides and proteins to reclaim nutrients. We have developed proprietary capabilities and expertise to engineer our product candidates to minimize their renal reabsorption. Based on data to date, we do not expect either of [^{225}Ac]Ac-AKY-1189 or [^{225}Ac]Ac-AKY-2519 to require renal protection strategies, such as pre-treatment with amino acids that are required for peptide-based radiopharmaceuticals targeting somatostatin-2 receptor, or SSTR2, such as Lutathera.
- *Broader number of addressable targets as compared to peptides.* Miniproteins, like antibodies, bind to targets with high affinity, which enables highly selective and potent binding to targets through protein-protein intermolecular contacts. This allows miniproteins to bind to many, diverse protein targets, whether or not the protein target has a cleft or other structural feature commonly required for peptide binders.
- *Enables rapid advancement to development candidates.* We utilize proprietary yeast surface display techniques that enable us to efficiently screen greater than five billion miniprotein variants and select the most promising candidates for advancement. Furthermore, unlike larger biologics, we couple biological *in vitro* evolution with medicinal chemistry. Medicinal chemistry utilizes solid phase peptide synthesis, which enables the rapid synthesis of miniproteins with site-specific modifications, including the incorporation of unnatural amino acids, to efficiently optimize our drug candidates to have beneficial characteristics likely to confer a strong clinical profile.
- *Enables rapid advancement into first-in-human evaluation.* Unlike larger biologics, which require time-consuming and expensive recombinant manufacture by cells in culture, miniproteins allow for efficient chemical synthesis using solid phase peptide synthesis and rapid and cost-effective scale-up.
- *Lack of manufacturing constraints*. For each clinically-administered dose, only microgram quantities of our miniprotein are anticipated to be required. The microdose quantities allow for small gram-scale batches of our miniprotein to be efficiently produced at contract manufacturers to enable development through first-in-human studies in contrast to other approved peptide drugs that require kilogram-scale batches.

We strengthen our miniprotein discovery workflow by incorporating artificial intelligence, or AI, technologies. We use various AI tools to help us select the best radiopharmaceutical biological targets, generate miniprotein libraries based on naturally evolved protein domains, design new miniprotein structures *de novo* using generative AI, and support our optimization efforts using machine learning models that are trained on our proprietary data. We can uniquely couple these state-of-the-art AI approaches with our wet-lab capabilities and our acquired expertise in discovery and optimization of miniprotein binders.

Manufacturing and supply

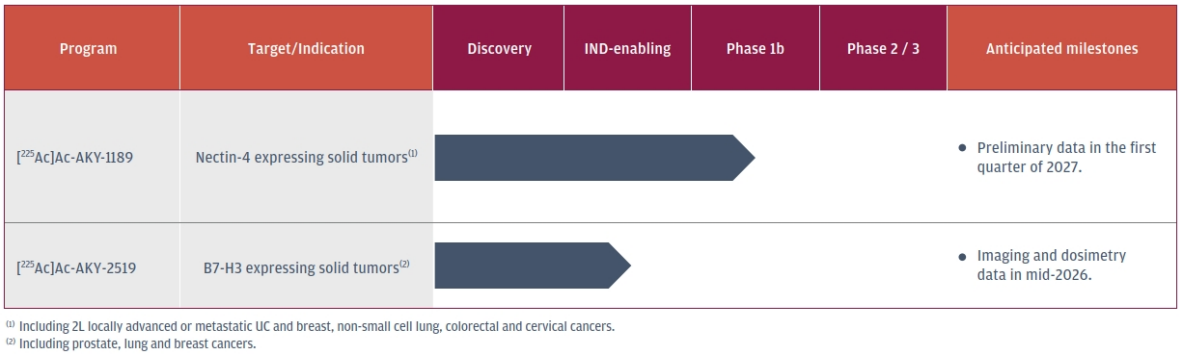
Manufacturing challenges and ensuring supply chain continuity and reliability have historically hindered the development and commercialization of radiopharmaceuticals. To overcome these challenges, we have established manufacturing and supply chain capabilities that are designed to be reliable and capital efficient with the ability to scale to meet global commercial demand for large cancer patient populations. Our end-to-end supply chain capabilities are orchestrated by our seasoned radiopharmaceutical development and manufacturing team that has experience advancing radiopharmaceutical programs from preclinical to commercialization. We have a state-of-the-art radiopharmaceutical development suite to apply our proprietary insights into process, formulation, and product development for preclinical, first-in-human, clinical trial, and commercial manufacturing and supply.

In addition, we have multiple domestic and international isotope supply agreements spanning therapeutic and diagnostic uses, including agreements with NorthStar Medical Technologies, LLC, TerraPower Isotopes, LLC and Niowave, Inc., among others, with priority access to ^{225}Ac.

We have partnered with leading contract manufacturing organizations to facilitate reliable and efficient supply, including co-located drug product manufacturing with ^{225}Ac and ^{64}Cu production to reduce costs, improve product turnaround time, and ease supply logistics, for our proprietary targeted miniprotein radiopharmaceutical precursors and products. Leveraging this network of partners, we are currently manufacturing drug product for our clinical trial. Additionally, we are building an internal cGMP radiopharmaceutical facility to enhance flexibility, increase control, and establish a hybrid internal and external clinical supply chain of our product candidates. We expect our manufacturing facility to be fully operational in the second half of 2026. As we grow our organization, we are continuing to evaluate options for internal commercial manufacturing to complement our network of commercial contract manufacturers.

Our pipeline

We are leveraging our proprietary miniprotein radioconjugate platform to discover and develop a deep pipeline of targeted radiopharmaceutical programs to address unmet needs in prevalent solid tumors. Our most advanced program, [^{225}Ac]Ac-AKY-1189, is targeting Nectin-4 expressing solid tumors, including locally advanced or metastatic UC, breast cancer, NSCLC, colorectal cancer and cervical cancer. Our second most advanced program, [^{225}Ac]Ac-AKY-2519, is targeting B7-H3 expressing solid tumors, such as prostate, lung and breast cancers.



(1) Including 2L locally advanced or metastatic UC and breast, non-small cell lung, colorectal and cervical cancers.
(2) Including prostate, lung and breast cancers.

Beyond [^{225}Ac]Ac-AKY-1189 and [^{225}Ac]Ac-AKY-2519, we have a robust discovery pipeline of several unpartnered miniprotein radioconjugate programs in the discovery phase that focus on clinically-validated targets. Our learnings from the optimization of [^{225}Ac]Ac-AKY-1189 are being applied to benefit the development of [^{225}Ac]Ac-AKY-2519 and these subsequent programs. We retain exclusive, worldwide development and commercialization rights to all our current product candidates and discovery programs. We also have a discovery collaboration with Eli Lilly and Company, or Eli Lilly, to generate novel anticancer radiopharmaceuticals against targets beyond the scope of our unpartnered pipeline programs.

[^{225}Ac]Ac-AKY-1189 targeting Nectin-4 expressing tumors

Our lead product candidate, [^{225}Ac]Ac-AKY-1189, was generated using our miniprotein radioconjugate platform and is designed to deliver ^{225}Ac, a highly potent alpha-emitting radioisotope, to Nectin-4 expressing tumors. Nectin-4 is a cell-surface protein found on a wide variety of tumors and has very limited expression in normal adult tissues. Nectin-4 is also the target of enfortumab vedotin, or Padcev, an approved ADC for the treatment of locally advanced and metastatic UC. Although Padcev has validated Nectin-4 as an oncology target, there has been limited clinical development activity to design other therapeutics targeting other Nectin-4 expressing tumors, which may be due to the need to develop a companion diagnostic for tissue testing when utilizing an ADC. In contrast, we intend to use imaging radioisotopes conjugated to AKY-1189 to readily select patients most likely to benefit from therapeutic treatment with [^{225}Ac]Ac-AKY-1189.

We believe AKY-1189, when conjugated to a radioisotope, has the potential to treat UC as well as other Nectin-4 expressing tumors by selectively delivering cytotoxic radioisotopes such as ^{225}Ac to Nectin-4 expressing tumors to kill the tumor. AKY-1189's short plasma half-life is designed to limit its radiation exposure to sensitive organs like bone marrow. We have also specifically designed AKY-1189 to minimize reabsorption by the kidneys to avoid potential toxicity concerns associated with renally-cleared radiopharmaceuticals.

In our preclinical studies, [^{225}Ac]Ac-AKY-1189 has demonstrated antitumor activity and increased overall survival in animals inoculated with Nectin-4 expressing cancer cell xenografts. It also demonstrated a compelling biodistribution profile, with low absorbed doses observed outside of the tumor, which supports [^{225}Ac]Ac-AKY-1189's potential to widen the therapeutic window. Furthermore, the Section 21 data included clinical imaging and dosimetry data from radioactive imaging radioisotope conjugates of AKY-1189, [^{68}Ga]Ga-AKY-1189 and [^{177}Lu]Lu-AKY-1189, which enabled assessment of tumor uptake and retention in 15 patients with solid tumors known to have high Nectin-4 expression, including UC, breast cancer, NSCLC, colorectal cancer and cervical cancer. In this assessment, AKY-1189 was observed to specifically localize and be retained in all tumor types examined, while being rapidly cleared from normal organs and tissues, including the kidney, with no adverse events observed. In this assessment, we also observed tumor uptake and retention at levels we expect to be sufficient to drive efficacious responses, based on similar measurements to those of leading marketed radiopharmaceuticals.

We have commenced a multi-site Phase 1b trial in the United States for the treatment of locally advanced or metastatic UC and other Nectin-4 expressing tumors and anticipate preliminary results from the Part-1 dose escalation portion of this trial in the first quarter of 2027. An imaging radioisotope is being used to directly assess tumor binding by AKY-1189 and identify patients most likely to respond to [^{225}Ac]Ac-AKY-1189 with the aim of delivering early clinical therapeutic signals across multiple Nectin-4 expressing tumor types. Patients determined to be Nectin-4 positive will move to the [^{225}Ac]Ac-AKY-1189 dose-escalation portion of the trial. That phase of the study will investigate increasing doses of [^{225}Ac]Ac-AKY-1189. Following completion of each dose level, safety of the drug will be assessed by a safety review committee and, if deemed safe, enrollment of the next higher dose level will commence. In December 2025, we disclosed that we had completed the first dose level of the Part 1 dose escalation of the Phase 1b clinical trial and had commenced enrollment of the next dose level. Enrollment in the trial remains on track, and we expect to present data from the Part 1 dose escalation in the first quarter of 2027. Upon completion of the dose escalation portion, a dose expansion portion will be conducted in patients with locally advanced or metastatic UC and other Nectin-4 expressing tumors. [^{225}Ac]Ac-AKY-1189 was granted Fast Track Designation by the FDA in February 2026 for the treatment of locally advanced or metastatic UC in patients who had progressed on or after prior systemic therapies.

[^{225}Ac]Ac-AKY-2519 targeting B7-H3 expressing tumors

Our second product candidate, [^{225}Ac]Ac-AKY-2519, is designed to deliver ^{225}Ac to B7-H3 (CD276) expressing tumors, including prostate, lung and other solid tumors. B7-H3 is a cell-surface protein that is highly expressed in many types of solid tumors, while having limited expression in normal tissues. We estimate that approximately 90% of all metastatic castration-resistant prostate cancers, 80% of NSCLCs and 70% of small cell lung cancers, express B7-H3, while also being expressed on other solid tumors like breast cancers. High expression of B7-H3 has been associated with poor overall survival outcomes and a lack of responsiveness to anti-PD-1 therapeutics in several tumor types. B7-H3 has attracted substantial clinical development efforts across different modalities, including ADCs, with several late-stage ADCs demonstrating preliminary efficacy signals and acceptable safety profiles. Regarding the potential for B7-H3 as a target in prostate cancer, we believe B7-H3 to be differentiated from PSMA for imaging and treatment due to its high tumor expression and limited expression in normal organs and tissues, such as kidneys and salivary glands.

In our preclinical studies, [^{225}Ac]Ac-AKY-2519 has demonstrated robust antitumor activity and increased overall survival in mice inoculated with B7-H3 expressing cancer cell xenografts. It also demonstrated a compelling biodistribution profile, with low absorbed doses observed outside of the tumor.

[^{68}Ga]Ga-AKY-2519 and [^{177}Lu]Lu-AKY-2519 uptake in tumors and normal tissue biodistribution is currently being assessed in patients with various B7-H3 expressing solid tumors. To date, each of [^{68}Ga]Ga-AKY-2519 and [^{177}Lu]Lu-AKY-2519 has demonstrated robust tumor uptake with low uptake in normal tissues and a differentiated biodistribution profile, showcasing rapid clearance from normal organ and tissues, including kidneys. We expect the results of the imaging and dosimetry assessment in patients with various tumor types to be reported in mid-2026. In March 2026, our INDs for [^{225}Ac]Ac-AKY-2519 and for [^{64}

Cu]Cu-AKY-2519 were cleared by the FDA to proceed to a Phase 1b clinical trial. We expect to initiate the multi-site Phase 1b clinical trial mid-2026.

Eli Lilly collaboration

In May 2024, we entered into a discovery collaboration with Eli Lilly to leverage our proprietary miniprotein radioconjugate platform to generate novel anticancer radiopharmaceuticals against targets beyond the scope of our unpartnered pipeline programs. We received a $60.0 million upfront cash payment in addition to an equity investment and are eligible to receive up to an additional $1.2 billion upon achievement of preclinical, clinical, regulatory, and commercial milestones, as well as tiered royalties. We are responsible for program discovery of a defined set of targets selected by Eli Lilly through initial human imaging studies and Eli Lilly is responsible for worldwide clinical development and commercialization from Phase 1 clinical trials onward. We retain worldwide rights to our proprietary pipeline programs, including our lead Nectin-4 targeting program.

Our team

We have assembled an experienced management team with deep expertise in drug development, approval, and commercialization, with members of our management being involved in the approval and commercialization of 14 currently marketed FDA-approved products. Our team is led by executives who have significant experience in company-building in the biopharmaceutical industry and a shared vision to build a leading radiopharmaceutical company. The experience of our President and Chief Executive Officer, Matthew Roden, PhD, in the biopharmaceutical industry includes leadership positions in corporate strategy and business development at Bristol Myers Squibb, and senior equity research coverage of the biotechnology sector at J.P. Morgan and UBS. He also serves as an Entrepreneur Partner at MPM BioImpact and on the Boards of Directors of other biotechnology companies. Our Chief Financial Officer, Kyle D. Kuvalanka, brings over 20 years of experience as a senior leader in the biopharmaceutical industry, having served in executive leadership roles at ROME Therapeutics, Syros Pharmaceuticals, Blueprint Medicines and Goldfinch Bio. Paul L. Feldman, PhD, our Chief Scientific Officer, was Co-founder and Chief Executive Officer of Phoundry Pharmaceuticals and, upon its acquisition by Intarcia Therapeutics, served as Head of Discovery and Translational Medicine at Intarcia. In his previous roles at GlaxoSmithKline, he was directly involved in the discovery of five approved drugs. Shulamit Ron-Bigger, PhD, our Chief Operating Officer, previously served as Head of Strategy and Operations for the Research and Early Development organization at Bristol Myers Squibb. Akos Czibere, MD, PhD, our Chief Medical Officer, has extensive experience in clinical development, most recently serving as Therapeutic Area Development Head of Hematology-Oncology at Pfizer. Dr. Czibere has been directly involved in the approval of six oncology drugs, including Elrexfio and Talzenna. Tyler Benedum, PhD, our Chief Technical Officer, previously served as Vice President of Chemistry, Manufacturing, and Controls Development at Avid Radiopharmaceuticals, a wholly-owned subsidiary of Eli Lilly, where he oversaw global commercial and clinical trial radiopharmaceutical manufacturing and played a key role in developing and advancing Amyvid and Tauvid through marketing authorization approval and commercialization.

Our company was co-founded by Todd Foley, a Managing Director at MPM BioImpact, who is currently Chair of our Board of Directors; Patrick Baeuerle, PhD, an MPM BioImpact Advisor, and currently a member of our Scientific Advisory Board; and Brian Goodman, PhD, a Partner at Vida Ventures.

Expanding the potential of radiopharmaceuticals

We believe that the field of radiopharmaceuticals is still in its infancy and is poised to become a fundamental pillar of cancer care and deliver transformative survival and quality of life outcomes for patients. External beam radiation therapy, or EBRT, has proven to be an effective option for cancer treatment but has limitations including lack of sufficient precision to avoid collateral damage to normal organs and tissues. Radiopharmaceuticals have the ability to deliver high levels of radiation directly and precisely to diseased tissue by combining the proven tumor-killing ability of radiation therapy with the high degree of molecular precision provided by their targeting components, offering cancer patients better outcomes than other anticancer modalities.

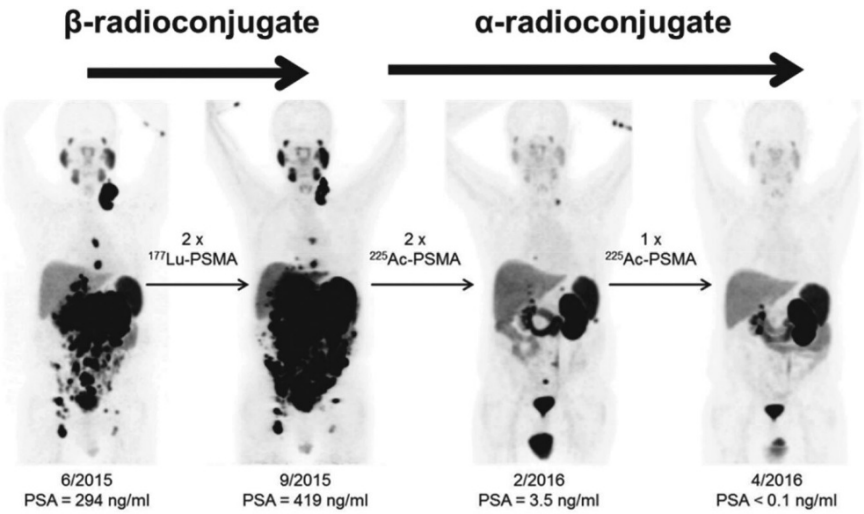
Several radiopharmaceutical drugs have been developed and commercialized in an expanding field, demonstrating the significant market potential of radiopharmaceuticals. Commercial adoption of Pluvicto and Lutathera, along with expanding operational and commercial infrastructure, positions radiopharmaceuticals as the next emerging modality. To date, the development of radiopharmaceutical candidates has been primarily focused on two biological targets: PSMA, the target of Pluvicto; and SSTR2, the target of Lutathera. Our company was founded with the aim of maximizing the impact of radiopharmaceuticals by bringing excellence to all aspects of radiopharmaceutical drug development, by discovering therapeutic candidates that broaden the set of targets and tumors that are addressed by radiopharmaceuticals. As a result, none of our programs target PSMA or SSTR2. We instead focus on leveraging our miniprotein radioconjugate platform to a broader set of addressable targets such as Nectin-4 and B7-H3, which are expressed in tumor types such as lung, breast, bladder, prostate and gastrointestinal tumors, and collectively account for an estimated 193,000 and 215,000 incident cases per year, respectively.

Radioisotopes used in radiopharmaceuticals fall into two classes: alpha-emitting and beta-emitting radioisotopes. Alpha particles are much larger and heavier than beta particles, with higher energy and shorter travel distances. Although both alpha-emitting and beta-emitting radioisotopes cause damage to the DNA of tumor cells resulting in tumor cell death, there are distinct differences. Beta-emitting radioisotopes create single-strand DNA breaks and can travel to more distant cells not in direct contact with the delivery point of the radiopharmaceutical. In contrast, alpha-emitting radioisotopes create catastrophic double-stranded

DNA breaks and are 1,000 times more potent in cell killing than beta-emitters but can only travel two to three cell lengths. Radiopharmaceuticals using alpha-emitting radioisotopes also offer advantages with administration as they result in less radiation exposure to the clinic staff during administration, as well as convenience to patients with no post-treatment restrictions on having contact with other people.

In third-party studies, alpha-emitting radioconjugates have also demonstrated increased anticancer activity in patients with tumors that did not respond to beta-emitting radioconjugates. As seen in the graphic below, a patient with widespread metastatic disease was observed to have progressive disease following treatment with two cycles of ^{177}Lu-PSMA-617. Subsequent treatment with ^{225}Ac-PSMA-617 resulted in profound regression of disease. Objective response rates of over 30% have been observed in academic trials of ^{225}Ac-PSMA-617, and a recent company-sponsored trial of ^{225}Ac-containing PSMA-617 radioligand showed a 43% response rate in patients previously treated with ^{177}Lu-containing PSMA-617 radioligand therapies. These results illustrate the powerful efficacy potential for ^{225}Ac-containing targeted radioconjugates.

Anticancer activity of alpha-emitting radioconjugates in patients with tumors that did not respond to beta-emitting radioconjugates



We believe alpha radioconjugates represent a significant opportunity for improved clinical outcomes for patients with cancer. Due to the inherent advantages and breakthrough efficacy potential, we are initially focused on alpha-emitting radioisotopes. However, our miniprotein radioconjugates have the ability to deliver both alpha-emitting and beta-emitting radioisotopes, which we believe expands the potential impact and tumor treatment options available for our radiopharmaceuticals.

Our proprietary miniprotein radioconjugate platform

We were founded to improve outcomes for cancer patients by pioneering a new class of targeted radiopharmaceuticals to unlock the benefit of the modality for prevalent tumor types that have historically been beyond the reach of radiopharmaceuticals. Our ability to leverage the killing power of a radioconjugate provides significant opportunity for discovering targeted radiopharmaceuticals with the potential to transform the cancer treatment paradigm for patients with a broad set of tumor types. Our aim is to discover targeting molecules that can bind with high affinity and prolonged duration on cancer cells to maximize efficacy, while having high selectivity and short residence time in the rest of the body to avoid toxicity to normal organs and tissues.

Our founders created our company with a focus on a category of polypeptides, referred to as miniproteins. Miniproteins consist of manifold scaffolds of less than one hundred amino acids in length that fold into a stable tertiary structure, making them larger than small peptides but smaller than large biologics. Similar to larger biologics, such as antibodies, miniproteins possess the ability to recognize and bind with high selectivity to a highly diverse set of tumor targets, but lack some of the known radiopharmaceutical property limitations of antibodies, including long circulating half-life and poor tumor uptake. Miniproteins also share some of the pharmacological profile advantages of small peptides such as high tumor penetration and short plasma half-life. However, miniproteins are able to bind to, and exhibit high selectivity for, tumor targets that are less tractable with smaller peptides. We believe miniproteins possess pharmacological properties that make them ideal targeting molecules for radiopharmaceutical product development, since they retain the advantages of large biologics and smaller peptides without the limitations specific to either class. We are focused on the discovery of novel miniproteins that are 40 to 70 amino acids in length, which categorizes them as biologics from a regulatory perspective, providing a twelve-year exclusivity period for approved products.

Our miniprotein radioconjugates offer both the potential for both potent antitumor activity and an enhanced safety and tolerability profile. The small size of miniproteins allows them to rapidly penetrate tumors. Furthermore, our miniprotein radioconjugates are able to internalize into cancer cells, which we believe drives prolonged retention. We have reproducibly

generated high affinity miniprotein binders to specific tumor targets. Tumor killing is achieved through delivery of absorbed radiation dose, which is enhanced by high tumor penetration, high binding affinity for tumor targets, and prolonged retention of drug in the tumor.

Two of the major concerns for toxicity with radiopharmaceuticals are renal damage due to radiation exposure in the kidney and hematological toxicity due to bone marrow exposure. The short plasma half-lives of miniproteins results in rapid clearance through the kidneys, limiting the overall radiation exposure of normal organs and tissues, such as the blood, bone marrow and skin, while the high target selectivity of our miniproteins further reduces off-target binding and exposure risk. We have built on this beneficial profile and engineered our product candidates to minimize their renal reabsorption using primary sequence modifications. Our lead optimization efforts have resulted in decreases in renal retention and increases in tumor uptake, which attributes are predicted to widen the therapeutic index of our product candidates relative to other radiopharmaceutical constructs.

Our miniprotein platform is designed to broaden the number of tumor targets addressable by radiopharmaceuticals. Our miniproteins bind to targets with high affinity, which enables highly selective and potent binding to targets through protein-protein intermolecular contacts and allows them to potentially bind to many protein targets, whether or not it has a cleft or other structural feature commonly required for peptide binders.

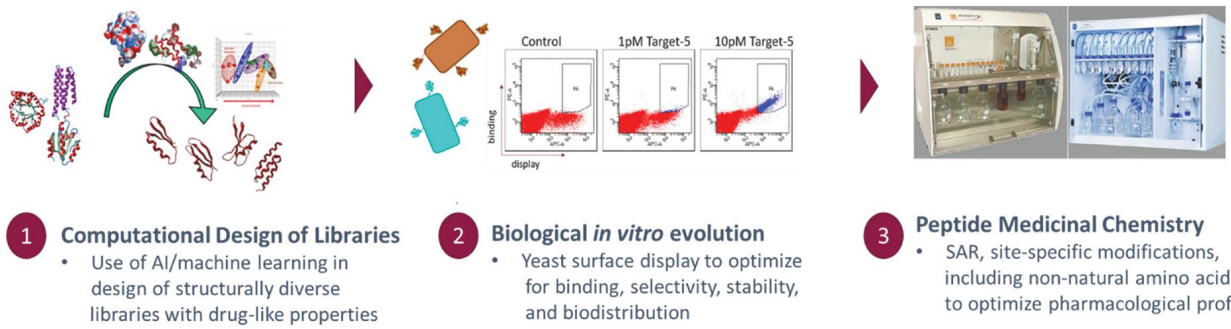
Our platform enables rapid advancement to product candidate and first-in-human evaluation. Miniproteins can be synthesized using solid phase peptide synthesis. This allows the evaluation of a large number of variants and enables the establishment of rich structure-activity relationships and site-specific modifications, including the incorporation of unnatural amino acids, to optimize for the desired drug-like properties.

Our proprietary miniprotein radioconjugate platform uniquely combines the following non-exhaustive list of technologies we use during our discovery process:

- novel, proprietary libraries of greater than 100 miniprotein scaffolds that enable yeast surface display selections of approximately five billion variants;
- machine-learning based design and optimization of miniprotein variants;
- unique biological assays to rapidly assess our miniprotein radioconjugate candidates; and
- medicinal chemistry enabling site-specific incorporation of proprietary unnatural amino acids into our miniprotein radioconjugates to optimize pharmacological properties.

We routinely apply our platform to rapidly generate and optimize miniprotein binders to tumor cell targets, not only selecting for product candidates that bind to their targets with high selectivity and affinity, but also optimizing for other properties that we believe will increase their potential as high-value therapeutics. As illustrated below, this iterative process to optimize miniproteins utilizes computational design with biological evolution and medicinal chemistry.

Iterative process optimizing miniprotein discovery combines computational design, biological evolution and medicinal chemistry.



Learnings from our Nectin-4 program and discovery programs have enabled additional technological advancements to be incorporated into subsequent programs, including our B7H3 program, to enhance our miniprotein radioconjugate platform and efficiently advance novel radiopharmaceutical programs.

Enhancing our discovery efforts by utilizing AI

AI, and its sub-categories of machine learning, deep learning, generative AI, and expert systems, are making a significant impact in the pharmaceutical industry and spawning many new companies and technologies. We have been utilizing AI to advance our miniprotein discovery and development over the past several years. Our reliance on AI has increased with advancement of AI tools, especially with accumulation of experimental data that informs AI models. Within discovery, we use AI tools to help us select radiopharmaceutical biological targets, generate miniprotein libraries based on naturally evolved protein domains, and design new

miniprotein structures *de novo* using generative AI. In addition, we apply machine learning to critical experimental datasets and use structure-based modeling to support optimization of our miniprotein binders.

Recent advances in *de novo* design software have been used to design small-molecule, peptide, macrocycle, and antibody binders to proteins. More recently, this software has been adapted and modified by us and others to design miniprotein binders to biological targets. We can uniquely couple these state-of-the-art AI approaches with our wet-lab capabilities and our acquired expertise in discovery and optimization of miniprotein binders.

We utilize AI tools throughout the entire process of advancing our radiopharmaceutical pipeline. In particular, we apply AI technology and yeast surface display to discover miniprotein binders to targets of interest in two ways: (1) to re-engineer naturally evolved protein-domain folds into libraries with hundreds of millions of variants each, from which target-binding miniproteins are captured by yeast surface display, and (2) to design novel miniproteins specifically for binding to biological targets of interest, and to use yeast surface display to identify the most successful designs.

In addition to our internal work using and advancing AI tools, we continue to assess potential third-party partners who are using AI tools, in order to further advance our specific discovery capabilities.

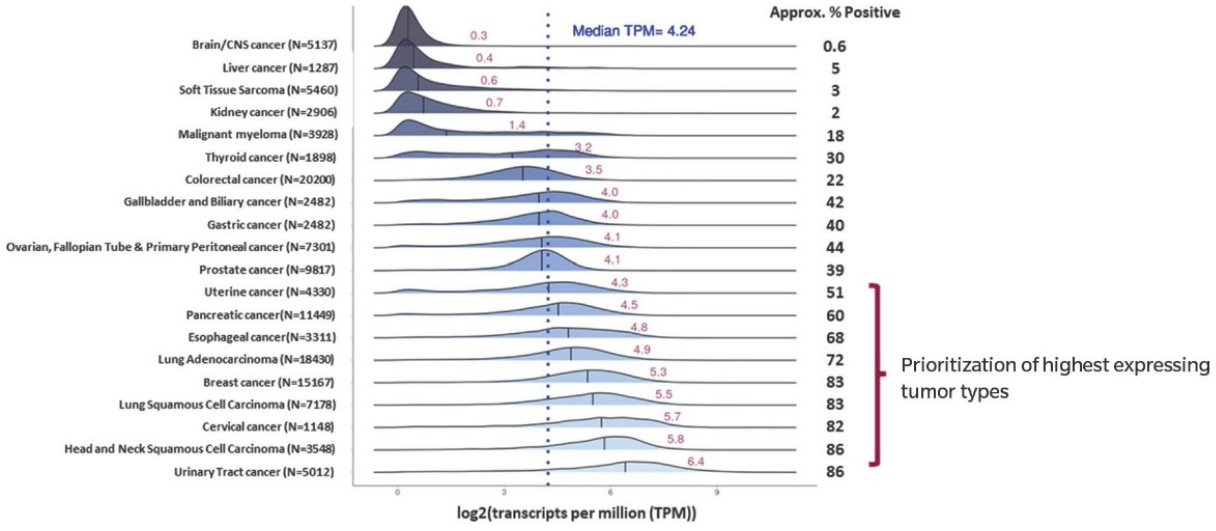
[^{225}Ac]Ac-AKY-1189: Our lead product candidate targeting Nectin-4 expressing tumors

Our lead product candidate, [^{225}Ac]Ac-AKY-1189, was discovered using our miniprotein platform and is designed to deliver ^{225}Ac, a highly potent alpha-emitting radioisotope, to Nectin-4 expressing tumors. The therapeutic potential of [^{225}Ac]Ac-AKY-1189 is supported by our preclinical studies and an investigator-initiated clinical imaging and dosimetry assessment demonstrating the ability of AKY-1189 radioconjugates to specifically localize to Nectin-4-expressing tumors and rapidly clear from normal organs and tissues. In April 2025, the FDA cleared our IND for [^{225}Ac]Ac-AKY-1189 for the treatment of locally advanced or metastatic UC and other Nectin-4 expressing tumors. We have commenced a multi-site Phase 1b clinical trial in the United States and anticipate preliminary results from the Part-1 dose escalation portion of this trial in the first quarter of 2027. [^{225}Ac]Ac-AKY-1189 was granted Fast Track Designation by the FDA in February 2026 for the treatment of locally advanced or metastatic UC in patients who had progressed on or after prior systemic therapies.

Nectin-4: a clinically validated oncology target

Nectin-4 is the target of Padcev which is approved worldwide for the treatment of locally advanced or metastatic UC. Nectin-4 is a surface protein that is expressed in a wide variety of solid tumor types and has very limited expression in normal adult tissues. Robust expression of Nectin-4 has been reported in various solid tumor indications, including UC, breast, NSCLC, colorectal, pancreatic, ovarian, cervical, head and neck, gastric, and esophageal cancers, with Nectin-4 expression levels of approximately 50%-95% observed in multiple tumor types. Up to an estimated 193,000 cancer patients are diagnosed annually in the United States with solid tumors that may express Nectin-4. The expression of Nectin-4 is associated with poor patient prognosis and unfavorable tumor progression. We believe that elevated Nectin-4 expression in these solid tumors supports our ongoing evaluation of [^{225}Ac]Ac-AKY-1189 in UC and beyond.

Elevated Nectin-4 mRNA expression expressed in multiple tumor types



Background on UC and other Nectin-4 expressing solid tumors

UC is a cancer that begins in the cells that line the urethra, bladder, ureters, renal pelvis and other organs. Over 90% of bladder cancers in the United States are UCs. The National Cancer Institute estimated that there would be greater than 83,000 new cases of bladder cancer and approximately 16,800 bladder cancer related deaths in the United States in 2024. Bladder cancer represents 4% of all cancers in the United States and is the fourth most common cancer in men, though less common in women. In 2024, the total number of patients with locally advanced or metastatic UC in the United States was estimated to be approximately 18,000. Annually, an estimated 4,200 patients are diagnosed with metastatic UC.

Until recently, the most common treatment for patients diagnosed with locally advanced or metastatic UC was chemotherapy with platinum-based drugs, such as carboplatin or cisplatin in combination with gemcitabine. Patients with metastatic disease that progressed during or after platinum-based chemotherapy were increasingly being treated with checkpoint immunotherapy. A number of PD-1 and PD-L1 checkpoint inhibitors have been approved by the FDA for use in refractory bladder cancer with objective response rates observed in clinical trials between 15% to 21%.

Due to the ubiquitous and robust expression of Nectin-4 in UC, no companion diagnostic or tissue testing for Nectin-4 is required. To date, there is only one approved Nectin-4 targeted therapy for UC, the ADC enfortumab vedotin, marketed as Padcev by Pfizer and Astellas. Padcev in combination with pembrolizumab is the standard of care for first-line treatment of patients with locally advanced or metastatic UC with no clear standard of care for subsequent lines of therapy. In locally advanced or metastatic UC patients previously treated with a PD-1 or PD-L1 inhibitor and/or platinum-based chemotherapy, treatment with Padcev monotherapy led to a 40.6% overall response rate and improved overall survival to 12.9 months compared to 9.0 months for patients treated with chemotherapy. In treatment-naïve patients with locally advanced or metastatic disease, Padcev in combination with pembrolizumab led to a 67.7% overall response rate and an overall survival of 31.5 months compared to 16.1 months for patients treated with chemotherapy. These data from Padcev in combination with pembrolizumab led to its recommendation as a first-line treatment for patients with locally advanced or metastatic bladder cancer. Sales of Padcev in 2024 were approximately $1.9 billion with estimated peak sales of up to $7.0 billion.

Although Padcev received initial regulatory approval from the FDA in 2019 for the treatment of locally advanced or metastatic UC, it has not been approved for the treatment of other Nectin-4-expressing tumors and there has been limited clinical development activity to design therapeutics targeting other Nectin-4 expressing tumors, which may be due to the need to develop a companion diagnostic for tissue testing when utilizing an ADC. In clinical trials leading to the initial approval of Padcev, Nectin-4 expression was observed in all 120 UC patients with available tumor biopsies, and the FDA agreed that the use of an *in vitro* diagnostic for Nectin-4 expression was not essential to the safe and effective use of Padcev.

Other cancers, including breast, NSCLC, colorectal and cervical have been shown to express Nectin-4, though overexpression may not be as ubiquitous as in UC. Breast cancer is the second most common type of cancer in women in the United States with more than an estimated 360,000 patients diagnosed in 2024. Lung cancer is the third most common cancer in the United States with 235,000 patients diagnosed annually and more people in the United States dying from lung cancer than any other type of cancer. NSCLC is the most common type of lung cancer, accounting for about 80% to 85% of all lung cancer cases. Colorectal cancer develops in the colon or rectum with 150,000 new cases in the United States estimated in 2024. Cervical cancer starts in the cells lining the cervix, the lower part of the uterus, and it is estimated that approximately 13,800 new cases of invasive cervical cancer were diagnosed in the United States in 2024.

We believe there is a significant opportunity to develop novel therapies with improved therapeutic profiles in these large patient populations with significant unmet medical needs.

Our solution: [^{225}Ac]Ac-AKY-1189

Our lead product candidate, [^{225}Ac]Ac-AKY-1189, contains a miniprotein, AKY-1189, that specifically binds to Nectin-4, which is conjugated via chelation to ^{225}Ac. AKY-1189 is a 45-amino-acid miniprotein covalently attached to an established radioisotope chelator, DOTA, through a short, chemically stable linker. In our preclinical mouse models, AKY-1189 was observed to specifically localize to Nectin-4 expressing tumors while minimizing exposure to the kidneys and other normal organs and tissues. Clinical imaging and dosimetry assessments using [^{68}Ga]Ga-AKY-1189 and [^{177}Lu]Lu-AKY-1189 in patients demonstrated high tumor uptake of AKY-1189 in UC and four other tumor types known to express Nectin-4, while being rapidly cleared from the body and avoiding normal organs and tissues.

Discovery and development of AKY-1189 utilizing our miniprotein radioconjugate platform

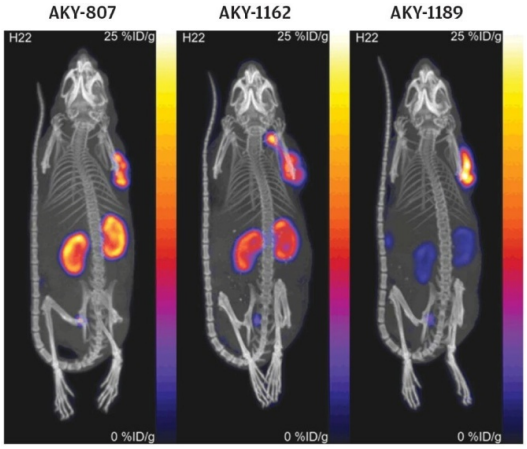
We have leveraged our proprietary miniprotein radioconjugate platform to discover and develop AKY-1189 following an evaluation of millions of potential candidates through a combination of computational modeling, directed evolution, functional screening, *in vivo* profiling and medicinal chemistry. Our approach enabled us to optimize the physicochemical, potency, and pharmacological properties of miniprotein binders that led to the discovery of AKY-1189.

AKY-1189 is engineered to be thermally stable to at least 75°C to enable the manufacture of [^{225}Ac]Ac-AKY-1189. The conjugated radiopharmaceutical is designed to maintain radiochemical stability for at least four days to support central manufacturing and enable flexible distribution and clinical administration.

The binding affinity, referred to as K_D, of AKY-1189 to Nectin-4 was determined to be 0.22 nanomolar, or nM, by surface plasmon resonance. The K_i, or inhibitory constant, which also measures binding affinity, of this miniprotein to Nectin-4 expressing tumor cells was determined to be 0.82 nM, and within the range of 0.1 nM to 1 nM targeted by therapeutic antibodies designed to deliver cytotoxins to tumors, such as ADCs. No off-target binding of AKY-1189 was detected when tested at a concentration of 450 times higher than its K_D for Nectin-4. This selectivity testing was conducted for more than 6,200 surface expressed or secreted proteins, including Nectin-1, -2, and -3. Furthermore, no binding was observed in a tumor cell line in which the gene for Nectin-4 had been removed by CRISPR knockout. We believe the binding affinity and selectivity of AKY-1189 supports a favorable risk-benefit profile.

In addition to high Nectin-4 binding affinity, we designed AKY-1189 to be minimally retained in the kidney. Our optimization process is exemplified by examining the progression of the properties from our earlier Nectin-4 targeted miniproteins, AKY-807 and AKY-1162, to AKY-1189. *In vitro* binding assays demonstrated that AKY-807 was a potent and selective binder to Nectin-4 expressing tumor cells but *in vivo* imaging studies with an imaging radioisotope, [^{111}In]In-AKY-807, demonstrated that the AKY-807 also localized to the kidneys. However, while some localization in the kidneys was expected given renally-cleared molecules are subject to reabsorption in the kidney, we observed that high levels remained in the kidneys for 22 hours after dosing. Through a series of sequence modifications to the miniprotein, we generated a series of molecules, including AKY-1162 and AKY-1189, that improved the Nectin-4 binding affinity and tumor binding, while simultaneously reducing kidney retention. As seen in the images below, there was considerable improvement in the lack of kidney retention, coupled with improvement in tumor uptake from AKY-807 to AKY-1162 to AKY-1189.

AKY-1189's rapid tumor uptake and kidney washout 22 hours after administration compared with previous miniproteins



Brightly colored areas depict presence of imaging radioisotope in mice implanted with xenograft tumors on right forelimb

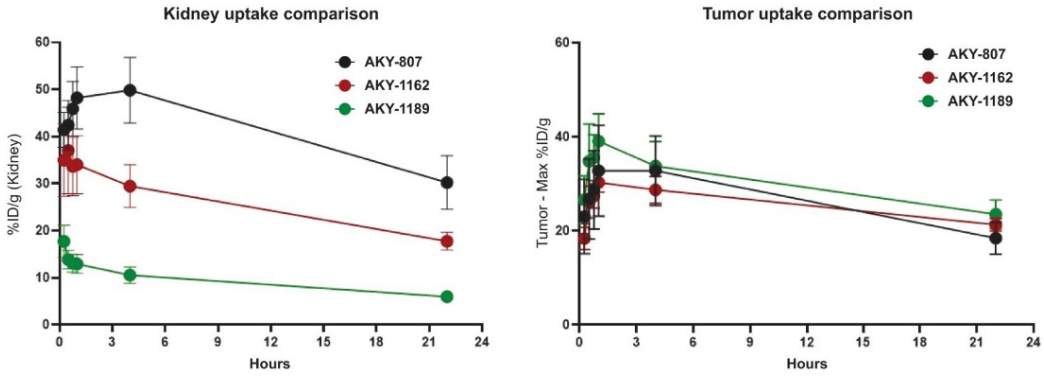


Figure left shows low kidney uptake and more rapid washout of AKY-1189 over 22 hours compared to other miniproteins. Figure right depicts more rapid and retained tumor uptake of AKY-1189 over 22 hours compared to other miniproteins.

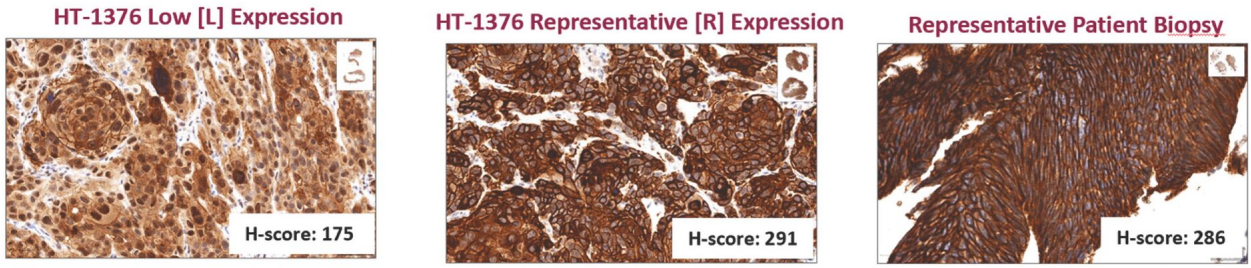
In vivo preclinical studies

Tumor and normal tissue uptake

To assess the potential of AKY-1189 in tumor xenograft models we used two versions of the HT-1376 human UC cell line, which is epithelial-like cell isolated from the urinary bladder of a patient with cancer. The expression levels were determined by

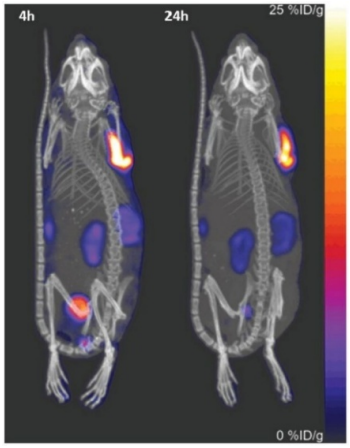
histochemical staining and scored using the Histochemical Scoring Assessment, or H-score, which has a range of 0-300, with higher scores representing higher expression. In one cell line, noted as low expression in the image below, Nectin-4 expression was limited to the endogenous levels of the cell line, with an H score of 175. In the other cell line, noted as representative expression in the image below, we used genetic engineering to increase the level of Nectin-4 expression to more closely match that observed in representative metastatic UC patient biopsies, with an H-score of 291. Between 55% to 90% of metastatic UC patients are initially diagnosed with a H-score similar to the representative expression cell line.

Nectin-4 expression in the modified HT-1376 cell line matched that observed in a representative biopsy from a metastatic UC patient that has high levels of Nectin-4 expression



We assessed the ability of AKY-1189 to localize to tumors in a mouse xenograft model using the representative Nectin-4 expressing HT-1376 cell line. Dosing with the imaging radioisotope [^{111}In]In-AKY-1189 allowed quantitative measurement of [^{111}In]In-AKY-1189 biodistribution using single-photon emission computed tomography, or SPECT, imaging. Within minutes of dosing, the highest levels of [^{111}In]In-AKY-1189 were found in the tumor. These levels in the tumor were maintained for approximately two hours, after which the levels slowly declined over the 24-hour observation period, with retention observed for up to three days after dosing. In contrast, the levels of [^{111}In]In-AKY-1189 observed in the kidneys rose within minutes after dosing and then rapidly declined as [^{111}In]In-AKY-1189 was eliminated from the body. This desired preclinical biodistribution profile, high tumor uptake and reduced exposure to organs and normal tissues, supported the advancement of [^{225}Ac]Ac-AKY-1189. We believe this biodistribution profile enables a wide therapeutic window for [^{225}Ac]Ac-AKY-1189 in treating patients with Nectin-4 expressing tumors.

AKY-1189 was localized and retained in tumors, while being rapidly washed out from the kidneys



Brightly colored areas depict presence of imaging radioisotope four hours after dosing (left) and 24 hours after dosing (right), in mice implanted with xenograft tumors on right forelimb

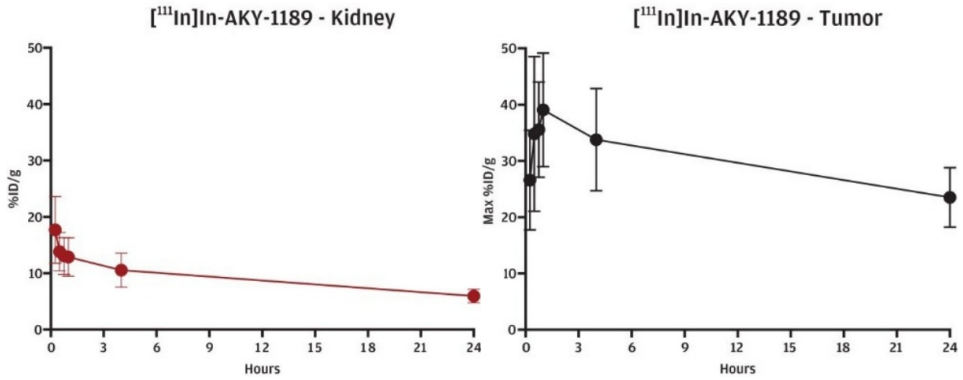


Figure left shows low kidney uptake and rapid washout of AKY-1189 over 24 hours. Figure right depicts high, rapid and retained tumor uptake of AKY-1189 over 24 hours.

Based on our modeling of the pharmacokinetics of AKY-1189 and scaling to projected human doses, we estimate that a dose of 7.4 MBq of [^{225}Ac]Ac-AKY-1189, a standard dose of ^{225}Ac-based radiopharmaceuticals that has demonstrated anticancer effects, will result in a low systemic and kidney exposure to radiation. The ability to deliver a radiopharmaceutical at a dose that is both safe and efficacious is critical and these preclinical predictions lie well within what we believe is a viable range for eventual clinical development and, if approved, commercialization. We believe that the therapeutic window of [^{225}Ac]Ac-AKY-1189 can improve tolerability and patient quality of life and provide the opportunity to potentially explore higher doses that could improve efficacy.

The profile of [^{225}Ac]Ac-AKY-1189 provides the potential for flexibility in both the schedule and administered dose before approaching the EBRT benchmark limit of 23 RBE5Gy for kidneys. This is a level at which EBRT has been associated with a risk of chronic kidney disease in five percent of patients five years after dosing.

Dosimetry scaling suggests that the radiation exposure to the kidney in humans will be well within the range generally considered to be acceptable in the field and below thresholds associated with kidney toxicity

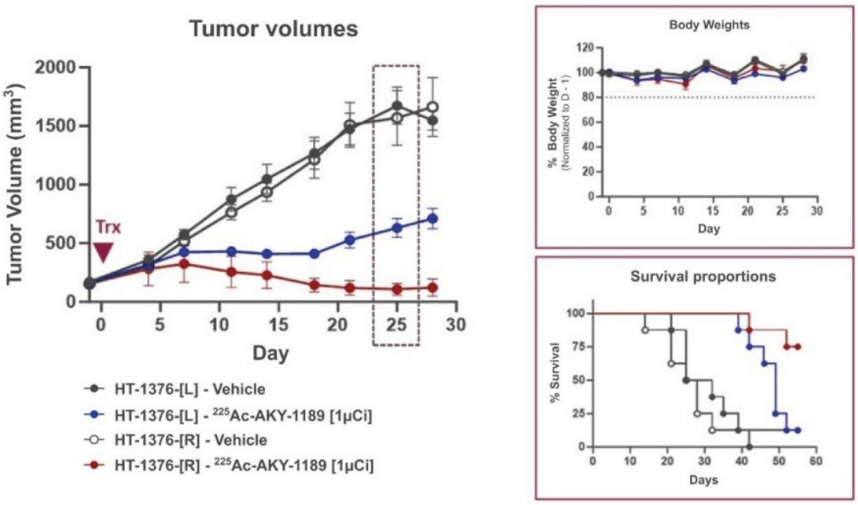
Compound	Absorbed Kidney Dose (RBE5Gy/MBq)[1]	Max Admi Activity (MBq)	Absorbed kidney dose after 6 admin (RBE5Gy)[2]
AKY-1189	0.17	137	7.6

[1] Absorbed dose to kidneys that would enable 6 doses at 7.4Mq is 0.52 RBE5Gy/MBq
[2] Assuming kidneys are the critical organ with an absorbed dose limit of 23 RBE5Gy

Antitumor activity of [^{225}Ac]Ac-AKY-1189

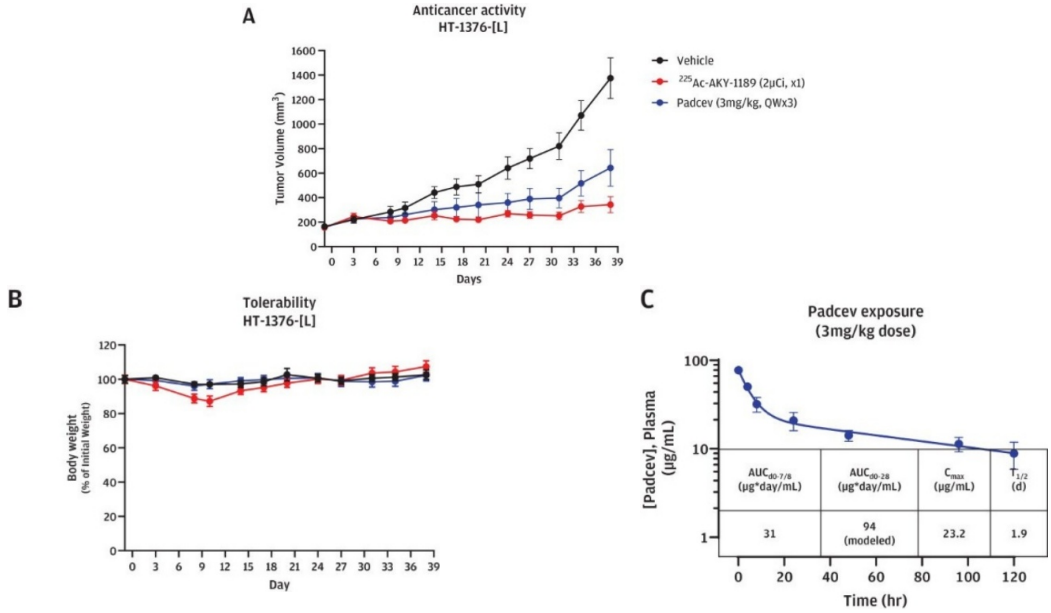
As shown below, [^{225}Ac]Ac-AKY-1189 also had increased antitumor activity in both high and low Nectin-4 expressing tumors in xenograft models. In our preclinical study, we observed that mice bearing HT-1376 tumors expressing low or representative levels of Nectin-4 were administered with either a single intravenous dose of 1 µCi, or microcuries, of [^{225}Ac]Ac-AKY-1189 or vehicle (n=8 mice per group). Treatment with [^{225}Ac]Ac-AKY-1189 resulted in a mean tumor regression of 53% in the representative Nectin-4 expressing tumors by day 25 (n=8 remaining animals) and an overall survival rate of 75% at the end of an eight-week observation period where median survival was not reached during the observation period. Treatment with vehicle in the representative Nectin-4 expressing tumors had no surviving animals at the end of the observation period and had a median overall survival of 28.5 days (n=5 remaining animals at day 25). In low Nectin-4 expressing tumors, [^{225}Ac]Ac-AKY-1189 treatment led to an average tumor growth inhibition of 62% at day 25 (n=8 remaining animals at day 25) and led to a median survival of 49 days. In low Nectin-4 expressing tumors, treatment with vehicle led to a median survival of 26.5 days (n=6 remaining animals at day 25). Body weight was monitored as a surrogate of overall animal health. Animal weights remained constant throughout the treatment period, indicating that [^{225}Ac]Ac-AKY-1189 treatment was well tolerated.

[^{225}Ac]Ac-AKY-1189 had increased antitumor activity in both high and low Nectin-4 expressing tumors in xenograft models



Furthermore, treatment of mice harboring HT-1376 tumors with a single dose of [^{225}Ac]Ac-AKY-1189 resulted in improved tumor growth inhibition compared to multiple doses of Padcev, assessed in the same study. The mice expressing low levels of Nectin-4 were treated with a single intravenous dose of 2 µCi of [^{225}Ac]Ac-AKY-1189 on day zero. As depicted below, this resulted in a mean tumor growth inhibition of 75% at day 38 compared to 53% inhibition after three administrations of Padcev on day zero, 7 and 14 (depicted in figure A below). Animal weights remained constant during the treatment period, indicating that both regimens were well-tolerated (depicted in figure B below). To compare the antitumor activity and tolerability of Padcev, we calculated the dose to be used in mice based off the approved clinical dose and regimen. The dosing regimen used for Padcev of 3mg/kg once a week for three weeks in mice, demonstrated plasma exposures with an area under the curve, or AUC, of 88 µg*day/mL (depicted in figure C below), similar to those observed in patients treated with the clinical regimen of 1.25mg/m^2 (AUC = 111+38 µg*day/mL). AUC is a measure of drug exposure over time. When comparing this clinically relevant dose of Padcev to [^{225}Ac]Ac-AKY-1189, we observed a favorable response for [^{225}Ac]Ac-AKY-1189 in Padcev responsive tumors.

A single administration of [^{225}Ac]Ac-AKY-1189 resulted in greater inhibition of tumor growth than Padcev in low Nectin-4 expressing tumors in xenograft models



C_{max} denotes maximum drug concentration; $T_{1/2}$ denotes time required to decrease drug concentration by half

Named patient use pursuant to Section 21 of South Africa's Medicines and Related Substances Act

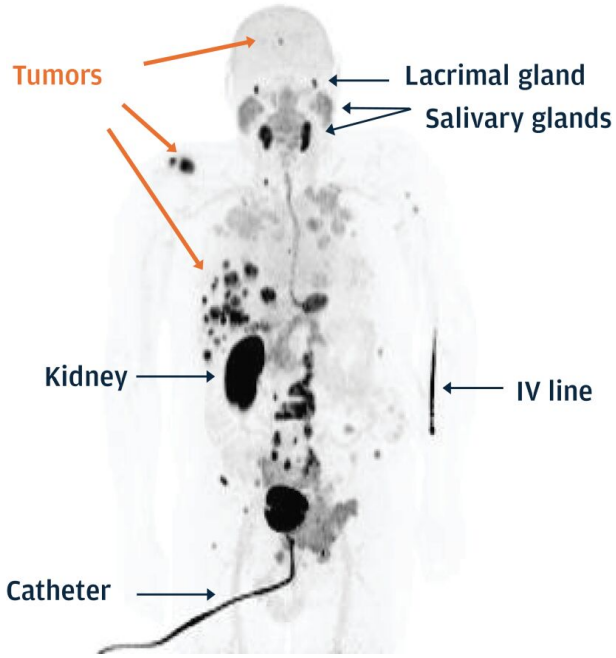
Mike Sathekge, MD, Head of Nuclear Medicine Department, University of Pretoria and Steve Biko, Academic Hospital, and President and Chief Executive Officer, Nuclear Medicine Research Infrastructure, or NuMeRI, administered radioconjugated AKY-1189 provided by us to a limited number of their patients in South Africa pursuant to Section 21 of the MRSA, which allows healthcare providers to administer unregistered medicines to patients, as authorized by SAPHRA.

AKY-1189 conjugated to an imaging radioisotope, [^{68}Ga]Ga-AKY-1189, was dosed in 20 patients with UC, breast cancer, NSCLC, colorectal cancer and cervical cancer. Of these 20 patients, all 20 were available for safety and normal tissue distribution assessment, and 15 were evaluable for tumor uptake. A subset of nine patients underwent kidney dosimetry with [^{177}Lu]Lu-AKY-1189 and eight patients were evaluable for quantitative assessment of the absorbed dose of radiation to the kidney and bone marrow. One patient also received

AKY-807 conjugated to the same imaging isotopes allowing for intra-patient comparison of tumor uptake and absorbed dose to the kidney. In line with the preclinical predictions, AKY-1189 showed superior tumor uptake with less radiation exposure to the kidneys compared to AKY-807, with no adverse events observed.

The figure below depicts normal tissue distribution of [^{68}Ga]Ga-AKY-1189, and robust tumor uptake, including in brain metastasis. Dark areas in the image below depict uptake of [^{68}Ga]Ga-AKY-1189.

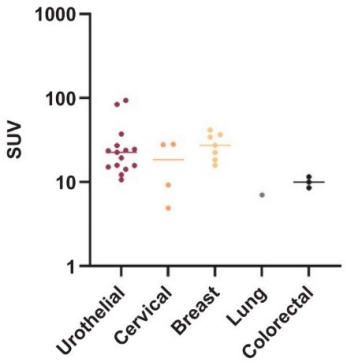
Representative PET/CT image of a patient dosed with [^{68}Ga]Ga-AKY-1189 after 1 hour



Tumor uptake was evaluated with [^{68}Ga]Ga-AKY-1189 in 15 patients via PET/CT one hour post-injection. Standard uptake values, or SUVs, were calculated using standard methodology also utilized in standard diagnostic PET/CT images. As depicted in the chart below, SUVs were consistently at or above the levels expected to be required for efficacy and in line with SUVs reported for approved radiopharmaceuticals. This was observed across all tumor types assessed including UC, breast cancer, NSCLC, colorectal cancer and cervical cancer, as depicted in the image below on the left. For context, in an editorial published in 2023, Michael Hofman depicted the observed SUV_{max} for various approved radiopharmaceuticals, including Pluvicto, Lutathera and

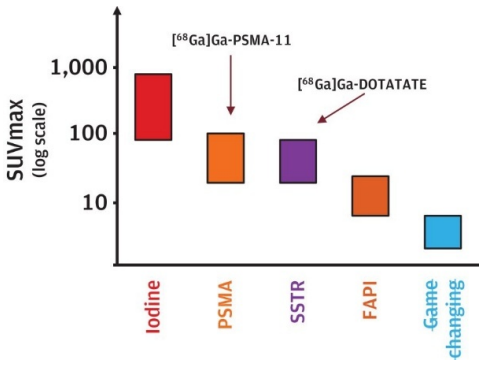
purported next alpha generation therapies. His study set forth the observed SUV_{max} for PSMA and SSTR in the range from 10-100, as depicted in the image below on the right.

[^{68}Ga]Ga-AKY-1189 tumor uptake across assessed tumor types suggests actionable therapeutic range



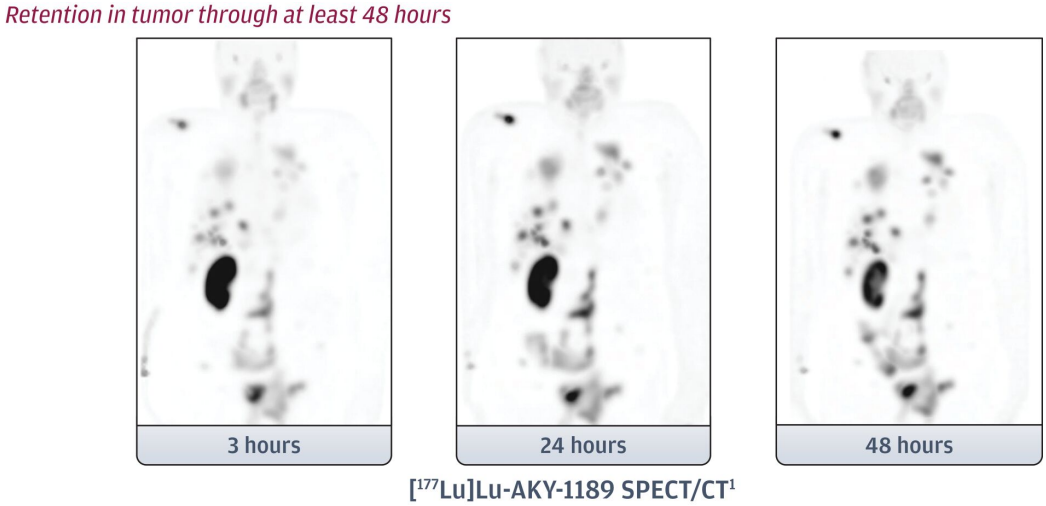
SUV in regions of interest including the primary and metastatic tumor deposits at 1 hour

Uptake of approved radiopharmaceuticals targeting PSMA and SSTR2



Hierarchy of SUVs: from left to right, iodine-131, PSMA, somatostatin receptor (DOTATATE), fibroblast activation protein inhibitor, and purported next-generation theranostics (referenced as "game changing" in the article).

Increasing tumor uptake with [^{177}Lu]Lu-AKY-1189 with no accumulation observed in normal tissues observed at 48 hours



[1] *~5.55 GBq (150mCi) administered activity*

The figures above depict normal tissue deposition and tumor uptake of [^{177}Lu]Lu-AKY-1189 during a 48-hour period. Dark areas in image depict tissue and tumor uptake of [^{177}Lu]Lu-AKY-1189. At 24 hours post administration, [^{177}Lu]Lu-AKY-1189 exposure increased in the tumors without accumulation of exposure to normal tissues.

The [^{177}Lu]Lu-AKY-1189 data suggests the predicted absorbed dose to the kidney (median absorbed dose of 0.30 gray/gigabecquerel, or Gy/GBq) and bone marrow (median absorbed dose: 0.01 Gy/GBq) allows for six or more therapeutic doses to be safely administered. These data are consistent with other approved radiopharmaceuticals, including Pluvicto, where the kidneys and bone marrow are not considered dose-limiting organs, when conjugated to either ^{177}Lu or ^{225}Ac. We plan to evaluate these findings in future clinical trials.

Our clinical development strategy

In April 2025, the FDA cleared our IND for [^{225}Ac]Ac-AKY-1189 for the treatment of locally advanced or metastatic UC and other Nectin-4 expressing tumors. We have commenced a multi-site Phase 1b clinical trial in the United States and anticipate preliminary results from the Part-1 dose escalation portion of this trial in the first quarter of 2027. The Phase 1b trial in the United States will enroll approximately 150 patients and follow a dose escalation strategy utilizing the Bayesian Optimal Interval, or BOIN,

design, which is a method used for early phase dose-finding based on model-assisted design elements and is used to determine a suitable dose for consideration in later-stage oncology trials. The Phase 1b trial will only enroll patients with locally advanced or metastatic UC in the dose escalation portion. Imaging and dosimetry in the United States trial will be done with [^{64}Cu]Cu-AKY-1189 allowing for multiple timepoint assessments through PET/CT. No imaging selection criteria are employed through dose escalation. Patients will receive up to six cycles of [^{225}Ac]Ac-AKY-1189 at increasing dose levels. Following completion of dose escalation, dose expansions will be conducted in locally advanced or metastatic UC (n=30), triple-negative breast cancer (n=30) and a basket cohort of other tumors known to have high Nectin-4 expression, including NSCLC, colorectal cancer and cervical cancer (n=40). The primary endpoint of the trial will be to assess safety and tolerability of [^{225}Ac]Ac-AKY-1189. Secondary endpoints include objective response rate (as measured by RECIST v1.1, a standard way to measure the response of a tumor to treatment), duration of response, progression-free survival, overall survival, changes in quality of life, and to characterize pharmacokinetic and pharmacodynamic profiles.

In December 2025, we disclosed that we had completed the first dose level of the Part 1 dose escalation of the Phase 1b clinical trial and had commenced enrollment of the next dose level. Enrollment in the trial remains on track, and we expect to present data from the Part 1 dose escalation in the first quarter of 2027. Upon completion of the dose escalation portion, a dose expansion portion will be conducted in patients with locally advanced or metastatic UC and other Nectin-4 expressing tumors. Based on the results of our trial, we plan to seek alignment with the FDA to conduct a pivotal Phase 2 trial for accelerated approval of [^{225}Ac]Ac-AKY-1189 for locally advanced or metastatic UC and other Nectin-4 expressing tumors. [^{225}Ac]Ac-AKY-1189 was granted Fast Track Designation by the FDA in February 2026 for the treatment of locally advanced or metastatic UC in patients who had progressed on or after prior systemic therapies.

[^{225}Ac]Ac-AKY-2519 targeting B7-H3 expressing tumors

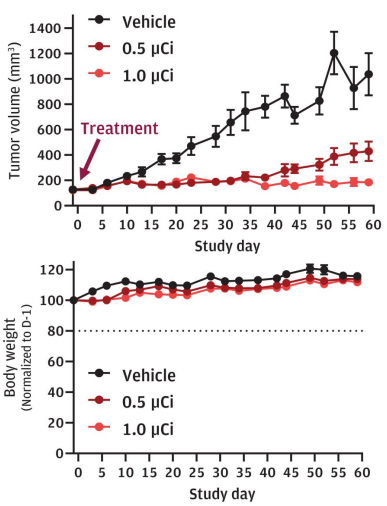
Our second product candidate, [^{225}Ac]Ac-AKY-2519, is designed to deliver ^{225}Ac to B7-H3 (CD276) expressing tumors, including prostate, lung and other solid tumors. B7-H3 is a cell-surface protein that is highly expressed in many types of solid tumors, while having limited expression in normal tissues. In the United States, an estimated 146,000 patients are diagnosed with metastatic NSCLC, small cell lung cancer or prostate cancer annually. We estimate that approximately 90% of all metastatic castration-resistant prostate cancers, 80% of NSCLCs and 70% of small cell lung cancers, express B7-H3, while also being expressed on other solid tumors like breast cancers. High expression of B7-H3 has been correlated with poor overall survival and a lack of responsiveness to anti-PD-1 therapeutics in several tumor types. B7-H3 has attracted substantial clinical development efforts across different modalities, including antibody-drug conjugates, with several late-stage antibody-drug conjugates demonstrating preliminary efficacy signals and acceptable safety profiles. Regarding the potential for B7-H3 as a target in prostate cancer, we believe B7-H3 may be superior to PSMA for imaging and treatment of patients with prostate cancer due to higher sensitivity and tumor specificity with a clean normal tissue expression profile.

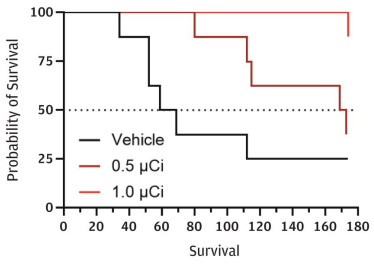
We discovered AKY-2519, a highly potent and specific binder of B7-H3, characterized it, and advanced it to a development candidate in the fourth quarter of 2024. AKY-2519, a proprietary 49-amino acid rationally designed miniprotein, met all of our pre-specified development candidate criteria including those for potency, selectivity, thermal stability, radiochemical stability, and solubility. AKY-2519 also met or exceeded our desired pharmacokinetic and biodistribution benchmarks while demonstrating robust preclinical efficacy.

Preclinical studies of [^{225}Ac]Ac-AKY-2519

As shown below, [^{225}Ac]Ac-AKY-2519 demonstrated dose-dependent antitumor activity after a single administration in mice harboring a non-small cell lung cancer cell, or NSCLC, line-derived xenograft tumor. Mice treated with a [^{225}Ac]Ac-AKY-2519 showed marked tumor growth inhibition of 92% for the 1.0 µCi dose and 80% for the 0.5 µCi dose, compared to vehicle (n=8 mice per group), and a best response of 48% regression at the 1.0 µCi group. The observed tumor growth inhibition led to prolonged survival for mice treated at each dose level compared to vehicle-treated mice. Body weight remained constant throughout the treatment period, suggesting that both dose levels of [^{225}Ac]Ac-AKY-2519 were well tolerated.

[^{225}Ac]Ac-AKY-2519 demonstrated antitumor activity and increased survival in xenograft models



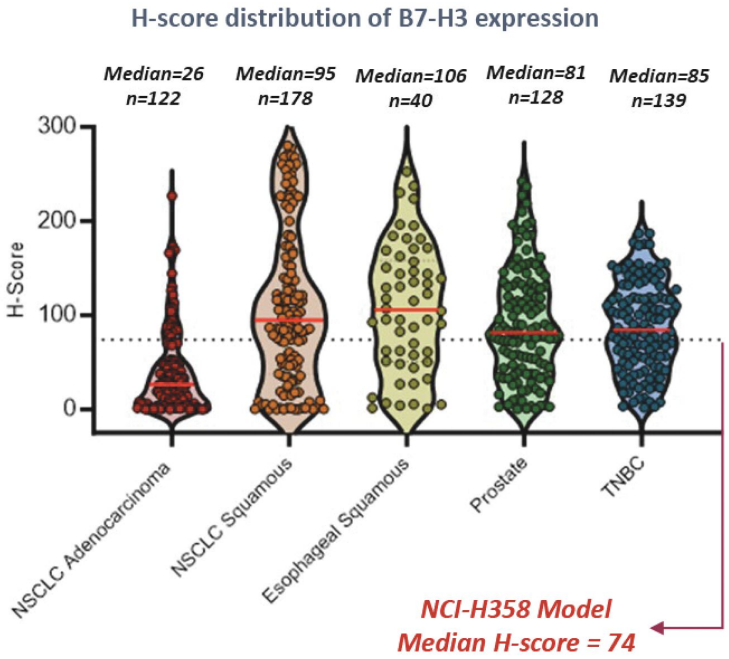


Median Survival

Group	Dose	Median Survival	P-Value
Group 1	Vehicle	64 days	N/A
Group 2	0.5 µCi	173 Days	0.055
Group 3	1.0 µCi	N/R	0.006

An analysis of B7-H3 expression across human tumor microarrays demonstrated that B7-H3 is highly expressed in multiple solid tumor indications, specifically squamous NSCLC, squamous esophageal, prostate and triple-negative breast cancers, or TNBC. Levels of B7-H3 expression across these indications are comparable to the level of expression of the mouse model utilized in our preclinical studies, supporting the translational relevance of this model and suggesting that a majority of patients in these indications express equivalent or higher levels of B7-H3 compared to the mouse model that responded robustly to [^{225}Ac]Ac-AKY-2519 treatment.

B7-H3 expression across multiple tumor types



Our development strategy for [^{225}Ac]Ac-AKY-2519

[^{68}Ga]Ga-AKY-2519 and [^{177}Lu]Lu-AKY-2519 uptake in tumors and normal tissue biodistribution is currently being assessed in patients with various B7-H3 expressing solid tumors. To date, each of [^{68}Ga]Ga-AKY-2519 and [^{177}Lu]Lu-AKY-2519 has demonstrated compelling tumor uptake across different tumor types with low uptake in normal tissues and a differentiated biodistribution profile, showcasing rapid clearance from normal organ and tissues, including the kidney. We expect the results of the imaging and dosimetry assessment in patients with various tumor types to be reported in mid-2026. In March 2026, our INDs for [^{225}Ac]Ac-AKY-2519 and for [^{64}Cu]Cu-AKY-2519 were cleared by the FDA to proceed to a Phase 1b clinical trial. We expect

to initiate the multi-site Phase 1b clinical trial mid-2026. We currently anticipate that the Phase 1b program will follow a dose escalation strategy utilizing the BOIN design. The Phase 1b program is planned to enroll patients with mCRPC, NSCLC or small cell lung cancer, using [^{64}Cu]Cu-AKY-2519 for dosimetry and imaging and [^{225}Ac]Ac-AKY-2519 for therapy. Following completion of dose escalation, dose expansions are planned for mCRPC and lung cancers. The primary endpoint will be to assess safety and tolerability of [^{225}Ac]Ac-AKY-2519. Secondary endpoints will include objective response rate (as measured by RECIST v1.1), duration of response, progression-free survival, overall survival, changes in quality of life, and to characterize pharmacokinetic and pharmacodynamic profiles.

Competition

The development and commercialization of new radiopharmaceutical products is highly competitive. We face and will continue to face competition from third parties that use radiopharmaceuticals and from companies focused on more traditional therapeutic modalities. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization of new products.

We consider our most direct competitors to be companies developing targeted alpha-based radiopharmaceuticals for the treatment of cancer. There are several companies developing targeted alpha-based radiopharmaceuticals for the treatment of cancer, including Abdera Therapeutics, Actinium Pharmaceuticals, Inc., Alpha9 Oncology, Inc., Artbio AS, Bayer AG, Convergent Therapeutics, Fusion Pharmaceuticals Inc. (acquired by AstraZeneca), Johnson & Johnson, Mariana Oncology, Inc. (acquired by Novartis AG), Perspective Therapeutics, POINT Biopharma Global Inc. (acquired by Eli Lilly), RadioMedix, Inc., Radionetics Oncology, RayzeBio, Inc. (acquired by Bristol Myers Squibb) and Telix Pharmaceuticals Limited. These companies are targeting a wide range of solid and hematologic malignancies using various alpha emitting isotopes, including radium-223, lead-212, and ^{225}Ac. The first and only approved alpha particle-based therapy is Bayer's Xofigo (radium-223) which is a salt of radium that cannot easily and robustly be attached to a targeting molecule, but naturally localizes to regions where cancer cells infiltrate bone. Xofigo was approved in 2013 for the treatment of prostate cancer with symptomatic bone metastases.

There are several companies with approved beta-emitting radiopharmaceuticals, including Lantheus Holdings, Novartis, Bayer, Sirtex, Boston Scientific and Q BioMed Inc. and other companies developing beta-emitting radiopharmaceuticals, including POINT Biopharma Global (acquired by Eli Lilly), ITM Isotope Technologies Munich SE, Y-Mabs and Telix Pharmaceuticals Limited. The beta emitting isotopes used by these companies include iodine-131, ^{177}Lu, strontium-89 and yttrium-90. A recently approved beta particle-based radiopharmaceutical is Novartis' Pluvicto, which was approved by the FDA in 2022 for the treatment of patients with metastatic prostate cancer.

Our competitors will also include companies that are or will be developing other treatment methods, including those utilizing other radioisotopes, as well as therapies for the same indications in oncology that we are targeting. In addition to the competitors we face in developing radiopharmaceuticals, we will also face competition in the indications we expect to pursue. To compete effectively with these existing therapies, we will need to demonstrate that our therapies are favorable to existing therapeutics and obtain comparable coverage and reimbursement for our product candidates.

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

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 or our collaborators may develop. Our competitors also may obtain FDA or other foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. Even if the product candidates we may develop in the future achieve regulatory approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Moreover, technological advances or products developed by our competitors may render our technologies or product candidates we may develop in the future obsolete, less competitive, or not economical. The key competitive factors affecting the success of [^{225}Ac]Ac-AKY-1189 and our other current and future product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Intellectual property

Our success depends in part on our ability to obtain, maintain, protect, defend and enforce proprietary protection for our product candidates and other discoveries, inventions, trade secrets and know-how that are critical to our business operations. Our success

also depends in part on our ability to operate without infringing, misappropriating or otherwise violating the intellectual property or proprietary rights of others, and in part on our ability to prevent others from infringing, misappropriating or violating our intellectual property or proprietary rights. A discussion of risks relating to intellectual property is provided under the section titled "Risk factors—Risks related to intellectual property."

With respect to our [^{225}Ac]Ac-AKY-1189 program, as of March 1, 2026, we own one pending international patent application filed under the Patent Cooperation Treaty, or a PCT Application, one issued U.S. patent, one pending U.S. non-provisional utility application and two pending foreign non-provisional patent applications in each of Taiwan and Argentina, which are directed to, among other things, composition of matter and uses of [^{225}Ac]Ac-AKY-1189. We do not own or license, and do not expect to own or license, any patents or patent applications that cover the radioactive payload in [^{225}Ac]Ac-AKY-1189, which is ^{225}Ac. The issued U.S. patent and any patents issuing from the patent applications we own or future patent applications that we may file based on these applications are expected to expire in 2044, excluding any patent term adjustments or extensions that may be available and assuming timely payment of all appropriate maintenance, renewal, annuity or other governmental fees.

With respect to our [^{225}Ac]Ac-AKY-2519 program, as of March 1, 2026, we own one pending PCT Application, one pending U.S. non-provisional utility application, and two pending foreign non-provisional patent applications in each of Taiwan and Argentina, which are directed to, among other things, composition of matter and uses of [^{225}Ac]Ac-AKY-2519. We do not own or license any issued patents related to our [^{225}Ac]Ac-AKY-2519 program. In addition, we do not expect to own or license any patents or patent applications that cover the radioactive payload in [^{225}Ac]Ac-AKY-2519, which is ^{225}Ac. Any patents issuing from the patent applications we own or future patent applications that we may file based on these applications are expected to expire in 2044, excluding any patent term adjustments or extensions that may be available and assuming timely payment of all appropriate maintenance, renewal, annuity or other governmental fees.

With respect to our platform program, as of March 1, 2026, we own one pending PCT Application, 22 pending non-provisional patent applications in each of Australia, Brazil, Canada, Chile, China, Colombia, Eurasia, Europe, Israel, India, Japan, Morocco, Mexico, Peru, Philippines, Saudi Arabia, South Africa, South Korea, Taiwan, Tunisia, United Arab Emirates, and the United States, and one pending U.S. provisional patent application. We do not own or license any issued patents related to our platform program. Any patents that issue from the patent applications we own or future patent applications that we may file based on these applications are expected to expire in 2043, 2045 and 2046, excluding any patent term adjustments or extensions that may be available and assuming timely payment of all appropriate maintenance, renewal, annuity or other governmental fees.

With respect to our discovery programs, as of March 1, 2026, we own one pending PCT Application, one pending U.S. provisional patent application, and four non-provisional patent applications (one each in China, Europe, the United States and South Africa), each of which is directed to compositions of matter and uses for miniproteins against our targets of interest. We do not own or license any issued patents related to our discovery programs. Any patents issuing from the patent applications we own or future patent applications that we may file based on these applications are expected to expire in 2043, 2044 and 2046, excluding any patent term adjustments or extensions that may be available and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

U.S. provisional patent applications are not eligible to become issued patents unless and until, among other things, we file one or more non-provisional U.S., foreign, and/or PCT Applications within 12 months of the first-filed provisional application to which these non-provisional applications claim priority. With regard to such U.S. provisional patent applications, if we do not timely file any non-provisional patent applications, we will lose our priority date with respect to subject matter and inventions disclosed in these provisional patent applications. Provided no statutory bars to patentability have occurred during the 12-month pendency of the provisional patent application, the option to refile and obtain a later filing date remains open. While we intend to timely file non-provisional patent applications related to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage. Further, our PCT Applications are not eligible to become patents until, among other things, we timely file national stage patent applications in jurisdictions that are party to the Patent Cooperation Treaty, and in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT Applications and any patent protection on inventions disclosed in such PCT Applications.

The proprietary nature of, and protection for, our product candidates and their methods of use are an important part of our strategy to develop and commercialize novel medicines. We have filed for or licensed patents rights relating to certain of our product candidates and are pursuing additional patent protection for them and for our other product candidates and technologies. In addition to patent protection, we also rely on trade secrets, know-how, trademarks, confidential information, other proprietary information and continuing technological innovation to develop, strengthen and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees, consultants, contractors and collaborators, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality and invention assignment agreements upon the commencement of employment or consulting relationships with us. However, such

confidentiality agreements can be breached, and we may not have adequate remedies for any such breach. For more information regarding the risks related to our intellectual property, see the section titled "Risk factors—Risks related to intellectual property."

License and collaboration agreements

Institute for Protein Innovation License Agreement

On November 1, 2021, we and the Institute for Protein Innovation, Inc., or IPI, entered into an Exclusive License Agreement, as amended on July 26, 2022, the IPI Agreement, pursuant to which IPI granted us an exclusive, worldwide license, with the right to sublicense (subject to certain conditions), under certain of IPI's patents and know-how related to certain binder proteins, targeting up to 14 target proteins, including Nectin-4, to research, develop, make, have made, and commercialize certain products. Pursuant to the IPI Agreement, IPI also granted us a non-exclusive license to certain intellectual property rights required to research, develop, make, have made, and commercialize certain products.

Upon execution of the IPI Agreement, we paid an upfront license fee of $0.2 million and are required to pay an annual license fee of less than $0.1 million until the first commercial sale of the first licensed product, pursuant to which we have paid an aggregate of $0.2 million through December 31, 2025. The IPI Agreement requires us to pay up to an aggregate of $24.0 million upon achievement of certain regulatory and development milestones. In addition, if we successfully commercialize a licensed product under the IPI Agreement, we are required to pay low single-digit royalties on net sales, on a product-by-product and country-by-country basis, subject to specified reductions, until the later of (a) the expiration of the last to expire valid claim covering the manufacture, use or sale of such licensed product in such country or (b) ten years after the first licensed product sale in such country. The royalties are subject to specified and capped reductions for payments owed to third parties for additional rights necessary to commercialize licensed products.

The IPI Agreement requires us to use diligent and commercially reasonable efforts to develop and commercialize a licensed product.

At any time after the fifth year anniversary of the IPI Agreement, if IPI receives a third-party request to license certain rights granted to us pursuant to the IPI Agreement for which we are not actively developing or commercializing a licensed product, we must either (i) submit a commercially reasonable development plan for such undeveloped field to IPI that we will put into effect within a certain number of days, (ii) substantiate why granting a license to such rights in such undeveloped field to the third party is not in our best business interest or (iii) enter into good faith negotiations with such third party for such rights in such undeveloped field.

Unless earlier terminated, the IPI Agreement will expire at the end of the last to expire royalty term. IPI may, at its election, either terminate the IPI Agreement, convert any of our exclusive license rights into non-exclusive rights, or choose to reduce the field or territory, if (a) the first commercial sale of a licensed product does not occur by January 1, 2035 or the payment of earned royalties, once begun, ceases for more than eight consecutive calendar quarters; (b) we default in the timely payment of any amount due or are otherwise in breach of the IPI Agreement and fail to remedy such default or breach within 30 days after written notice thereof; (c) we are found, on more than one examination, to have underreported or underpaid any royalty payment by more than five percent in any three calendar quarters in the period under examination; (d) we cease to carry on our business related to the subject matter of the licensed patents or (e) we become insolvent or file a petition regarding bankruptcy or insolvency or other certain insolvency or bankruptcy-related events occur. We may terminate the IPI Agreement in its entirety, with or without cause, upon 60 days' written notice.

TRIUMF License Agreement

On July 21, 2022, we and TRIUMF Inc., a Canadian non-profit, or TRIUMF, TRIUMF Innovations, Inc., a Canadian non-profit, the University of British Columbia, and BC Cancer, a provincial health services authority, entered into a License Agreement, the TRIUMF License. Pursuant to the TRIUMF License, TRIUMF, the University of British Columbia and BC Cancer, or the Licensors, granted us a non-exclusive, worldwide license, with right to sublicense (subject to certain conditions), under certain patents and know-how related to the Licensors' chelator technology to make, use, sell, offer for sale, import, and export certain radiopharmaceutical products for the diagnosis, treatment, amelioration, and prevention of human diseases and conditions. None of our product candidates currently incorporate, or rely on, the licensed patents and know-how from the TRIUMF License.

We paid an initial license fee of $0.1 million upon execution of the TRIUMF License. The TRIUMF License requires us to pay up to an aggregate of $2.0 million upon achievement of certain regulatory and development milestones. We are also obligated to pay low single digit royalties on net sales of licensed products, on a product-by-product basis.

For licensed products not covered by a valid claim of a licensed patent, our royalty obligation terminates on the tenth anniversary of the first commercial use of such licensed product in each country.

Unless earlier terminated, the TRIUMF License will expire on the later of the twelfth-year anniversary of the TRIUMF License or the expiry of the last patent subject to the TRIUMF License. We may terminate the TRIUMF License for convenience upon 60 days' written notice. The Licensor may, at its option, terminate the TRIUMF License if (i) we become insolvent, cease to carry on business or other certain insolvency or bankruptcy-related events occur, (ii) we breach certain provisions (including those related to sublicenses, confidentiality, and insurance), (iii) the licensed patents and know-how become subject to any security interest, lien,

charge or encumbrance in favor of a third party through our action or (iv) there is an uncured breach by our sublicensee and we do not terminate the respective sublicense agreement. Either party may terminate the TRIUMF License for uncured breach, subject to specified cure periods.

University of Minnesota License Agreement

On March 3, 2023, we and the Regents of the University of Minnesota, or the University of Minnesota, entered into an Exclusive License Agreement, the Minnesota License, pursuant to which the University of Minnesota and the Stanford University, or Stanford, granted us, solely for human and veterinary uses, an exclusive license under the University of Minnesota's and Stanford's rights in certain patents related to certain binding proteins to make, use, sell, offer for sale, and import certain therapeutic and diagnostic products in the countries where there are licensed patents and a non-exclusive license to use licensed technical information. None of our product candidates incorporate, or rely on, the patents and know-how from the Minnesota License.

We paid an upfront fee of $0.1 million upon entering into the Minnesota License and paid an annual license fee of less than $0.1 million throughout the term of the Minnesota License, pursuant to which we have paid an aggregate of $0.4 million through September 30, 2025. No milestones were achieved under the Minnesota License prior to the termination of this agreement.

In July 2025, we provided notice to the University of Minnesota to terminate the Minnesota License and paid the $10,000 early termination fee, with an effective termination date of September 9, 2025.

Eli Lilly and Company License, Research and Collaboration Agreement

On May 16, 2024, we and Eli Lilly entered into a License, Research and Collaboration Agreement, the Collaboration Agreement. Pursuant to the Collaboration Agreement, we granted Eli Lilly an exclusive (even as to us and our affiliates), royalty-bearing, worldwide license, with the right to sublicense, to certain of our patents and other intellectual property rights to exploit certain compounds and therapeutic or diagnostic products that contain such compounds solely as products that contain a radioactive isotope. We also granted Eli Lilly a non-exclusive, royalty-bearing, worldwide license, with the right to sublicense, to the intellectual property necessary or useful to exploit the licensed compounds and licensed products solely as products that contain a radioactive isotope and a non-exclusive, fully paid-up license, with the right to sublicense, to exploit certain other intellectual property developed under the Collaboration Agreement for any and all purposes (subject to certain limitations). In addition, we and Eli Lilly agreed to negotiate in good faith to enter into a separate agreement in the event the parties agree that the clinical development of a licensed compound requires, or would be benefited by, a license to one of our other compounds.

Under the Collaboration Agreement, Eli Lilly may designate a specified number of initial collaboration targets, with the right to substitute other targets. We will be responsible for research activities through initial human imaging studies for a lead candidate for each selected target, and Eli Lilly will thereafter be responsible for regulatory filings, clinical development and commercialization activities worldwide. There is a separate research plan for each collaboration target, and our development costs are capped, on a research plan-by-research plan basis. Eli Lilly will reimburse our reasonable out-of-pocket costs and full-time equivalent costs incurred in excess of the cap.

Eli Lilly paid us an upfront license fee of $60.0 million upon execution of the Collaboration Agreement. The Collaboration Agreement requires Eli Lilly to pay up to an aggregate of $525.0 million upon achievement of certain research, development, regulatory and commercial launch milestones and up to an aggregate of $630 million upon achievement of certain sales milestones. In addition, if Eli Lilly successfully commercializes a therapeutic or diagnostic product under the Collaboration Agreement, Eli Lilly is required to pay us tiered royalties of up to 10% based on annual net sales, on a product-by-product and country-by-country basis, subject to specified reductions, until the later of the expiration of licensed patent rights in a country, expiration of regulatory exclusivity, or ten years after the first product sale in such country. The Collaboration Agreement requires Eli Lilly to use commercially reasonable efforts to develop and commercialize a licensed product from a research program in certain markets and through satisfaction of certain criteria.

Unless earlier terminated, the Collaboration Agreement will continue on a licensed product-by-licensed product and country-by-country basis until the expiration of the applicable royalty term for such licensed product. Either party may terminate the Collaboration Agreement for uncured material breach, subject to specified cure periods. In certain instances, if Eli Lilly has the right to terminate the Collaboration Agreement for our uncured material breach, Eli Lilly may, at its option, continue the Collaboration Agreement where all payments due from Eli Lilly to us, on a prospective basis, will be reduced by a specified percentage and Eli Lilly diligence and reporting obligations will end. Eli Lilly may, at any time and without cause, terminate the Collaboration Agreement in its entirety or on a collaboration target-by-collaboration target or region-by-region basis upon sixty days' notice.

In connection with the Collaboration Agreement, we and Eli Lilly entered into a Series A-1 redeemable convertible preferred stock purchase agreement pursuant to which we issued and sold an aggregate of 2,500,000 shares of our Series A-1 redeemable convertible preferred stock at a purchase price of $4.00 per share for aggregate net proceeds of $10.0 million.

Government regulation

Government authorities in the U.S., including federal, state, and local authorities, and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, and export and import of biological products, such as those we are developing. In addition, some government authorities regulate the pricing of such products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Review and approval for licensing biologics in the U.S.

In the U.S., the FDA regulates biological products under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. FDA approval is required before any biological product can be marketed in the U.S. Biological products are also subject to other federal, state, and local statutes and regulations. If we fail to comply with applicable FDA or other requirements at any time during the product development process, clinical testing, the approval process or after approval, we may become subject to administrative or judicial sanctions or other consequences, including the FDA's refusal to allow us to proceed with clinical testing, issuance of clinical holds for planned or ongoing studies, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, issuance of untitled or warning letters, product recalls, product seizures, import detentions or refusals, total or partial suspension of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution. Any such action could have a material adverse effect on us.

The process required by the FDA before product candidates may be marketed in the U.S. generally involves the following:

- completion of extensive nonclinical laboratory tests and nonclinical animal studies in compliance with applicable good laboratory practices, or GLP, requirements;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin in the U.S. and must be updated annually;
- approval by an independent institutional review board, IRB, or ethics committee representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCPs, to establish the safety and efficacy of the product candidate for each proposed indication;
- manufacture of the drug substance and drug product in accordance with the FDA's cGMP requirements, along with required analytical and stability testing;
- preparation of and submission to the FDA of a biologics license application, or BLA, requesting marketing approval for one or more proposed indications, that includes sufficient evidence of establishing the safety, purity and potency of the proposed biological product for its intended indication, including from results of nonclinical testing and clinical trials;
- review of the product application by an FDA Advisory Committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the proposed product is produced to assess compliance with cGMPs and to assure that the facilities, methods, and controls are adequate to preserve the product's identity, quality, and strength;
- satisfactory completion of any FDA audits of the nonclinical studies and clinical trial sites to assure compliance with GLPs and GCPs, as applicable, and the integrity of data in support of the BLA;
- payment of user fees under the Prescription Drug User Fee Act, or the PDUFA, unless exempted; and
- the FDA's review and approval of the BLA.

The nonclinical and clinical testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Nonclinical studies and investigational New Drug Application

Before testing any biological product in humans, a product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of product chemistry, formulation, and stability, as well as in vitro and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulation and requirements, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND.

An IND is a request for authorization from the FDA to administer an investigational biological product to humans in clinical trials in the U.S. The central focus of an IND submission is on the general investigational plan, the protocol(s) for human trials and the safety of trial participants. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls

information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence.

At any time during the initial 30 day IND review period or while clinical trials are ongoing under the IND, the FDA may impose a partial or complete clinical hold. Clinical holds may be imposed by the FDA when there is concern for patient safety, and may be a result of new data, findings, or developments in clinical, nonclinical, and/or chemistry, manufacturing and controls or where there is non-compliance with regulatory requirements. A clinical hold would delay either a proposed clinical trial or cause suspension of an ongoing trial, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed. A separate submission to an existing IND must also be made for each successive clinical trial to be conducted, and the FDA must grant permission, either explicitly or implicitly by not objecting, before each clinical trial can begin.

Clinical trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the inclusion and exclusion criteria, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

Additionally, approval must also be obtained from each clinical trial site's IRB, before the trials may be initiated and the IRB must monitor the trial until completed. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, the safety of human subjects and the possible liability of the institution. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries, including on clinicaltrials.gov.

The clinical investigation of a biological product is generally divided into three or four phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

Phase 1. The investigational product is initially introduced into healthy human subjects or, in the case of some products designed to address severe or life-threatening diseases, patients with the target disease or condition. These trials are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.

Phase 2. The investigational product is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy.

Phase 3. The investigational product is administered to an expanded patient population, generally at geographically dispersed clinical trial sites to generate enough data to statistically evaluate safety, purity and potency, to evaluate the overall benefit-risk profile of the investigational product, and to provide an adequate basis for physician labeling.

Phase 4. In some cases, the FDA may condition approval of a BLA for a product candidate on the sponsor's agreement to conduct additional clinical trials after approval or a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the biological product. Such post-approval trials are typically referred to as Phase 4 clinical trials.

Sponsors must also report to the FDA, within certain timeframes, serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the product candidate. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data and safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

A sponsor of an investigational biological product for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational biological product. This requirement applies on the earlier of the first initiation of a Phase 2 or Phase 3 trial of the investigational biological product or, as applicable, 15 days after the biological product receives a designation as a breakthrough therapy or fast track product.

Concurrent with clinical trials, sponsors usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality, and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

During the development of a new biologic, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 1, at the end of Phase 2, and before a BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development.

Submission of a BLA to the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, detailed investigational product information is submitted to the FDA in the form of a BLA requesting approval to market the product for one or more indications. Under federal law, the submission of most BLAs is subject to an application user fee, and the sponsor of an approved BLA is also subject to an annual program fee for each approved biological product on the market. Applications for orphan drug products are exempted from the BLA application fee and may be exempted from program fees, unless the application includes an indication for other than a rare disease or condition.

A BLA must include all relevant data available from pertinent nonclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including trials initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational product to the satisfaction of the FDA.

The FDA conducts a preliminary review of all BLAs within the first 60 days after submission before accepting them for filing to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an application for filing. Under the performance goals and policies implemented by the FDA under PDUFA, once a BLA has been submitted, the FDA's goal for novel biological products generally is to review the application within ten months after it accepts the application for filing, or, if the application is granted priority review, six months after the FDA accepts the application for filing. The FDA does not always meet its PDUFA goal dates, and the review process may be extended. For example, the review process and the PDUFA goal date may be extended by three months if the FDA requests or if the applicant otherwise provides additional data, analysis or information that FDA deems a major amendment.

Before approving a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect the sponsor and one or more clinical sites to assure compliance with GCPs. Material changes in manufacturing equipment, location, or process post-approval, may result in additional regulatory review and approval.

The FDA is required to refer an application for a novel biological product to an advisory committee or explain why such referral was not made. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA's decision on a BLA

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA inspections of nonclinical and clinical trial sites to assure compliance with GLPs or GCPs, the FDA may approve the BLA or issue a complete response letter. Under the PHSA, the FDA may approve a BLA if it determines the product is safe, pure, and potent, and that the facility in which the product will be manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, purity and potency. If the FDA determines the product meets those standards, it may issue an approval letter authorizing commercial marketing of the biological product with specific prescribing information for specific indications. If the application is not approved, FDA will issue a complete response letter, which indicates that the review cycle of the application is complete and the application is not ready for approval. A complete response letter will identify the deficiencies that prevent the FDA from approving the application and may require additional clinical data or an additional Phase 3 clinical trial(s), or other significant, expensive and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval and issue a denial.

The FDA could also approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, program to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

Orphan drug designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the U.S. for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Additionally, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor, or the sponsor is unable to provide sufficient quantities. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar, but not identical, benefits.

The FDA has historically taken the position that the scope of orphan exclusivity aligns with the approved indication or use of a product, rather than the disease or condition for which the product received orphan designation. However, in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with this position, holding that orphan-drug exclusivity blocked the FDA's approval of the same drug for all uses or indications within the same orphan-designated disease. On January 24, 2023, the FDA published a notice in the Federal Register to clarify that the FDA intends to continue to apply its longstanding interpretation of the regulations to all matters outside of the scope of the Catalyst order and will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of orphan drug exclusivity.

Expedited review programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. New biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic may request that the FDA designate the biologic as a fast track product at any time during the clinical development of the product. The sponsor of a fast track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a biologic submitted to the FDA for approval, including a product candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review. An application for a biological product will receive priority review designation if it is for a biological product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological product designated for priority review in an effort to facilitate the review. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Fast track designation, breakthrough therapy designation, and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Accelerated approval

Product candidates studied for their safety and effectiveness in treating serious conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA may require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a biologic or indication approved under accelerated approval if, for example, the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the FDA, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to FDA for review during the pre-approval period. After 120 days following marketing approval, unless otherwise informed by the FDA, advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Project Optimus

In 2021, the FDA's Oncology Center of Excellence launched Project Optimus, an initiative to reform the dose optimization and dose selection paradigm in oncology drug development to emphasize selection of an optimal dose, which is a dose that maximizes not only the efficacy of a drug but also its safety and tolerability.

Project Optimus was driven by the FDA's concerns that the historical approach to dose selection, which generally determined the maximum tolerated dose, may have resulted in doses and schedules of molecularly targeted therapies that were inadequately characterized before the initiation of pivotal trials.

Project Optimus requires the implementation of strategies for dose finding and dose optimization that leverage nonclinical and clinical data in dose selection, including randomized evaluations of a range of doses in trials. This initiative emphasizes the performance of dose finding and dose optimization studies as early and efficiently as possible in development programs. In support of this initiative, the FDA may request sponsors of oncology product candidates to conduct dose optimization studies.

Post-approval requirements

Biological products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new dosage forms, indications or other labeling claims, are subject to prior FDA review and approval.

Biological product manufacturers are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections for compliance with cGMPs. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Manufacturers and manufacturers' facilities are also required to comply with applicable product tracking and tracing requirements and notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the U.S. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

A biological product may also be subject to official lot release, meaning that the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release, the manufacturer must submit samples of each lot, together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot, to the FDA. The FDA may perform certain confirmatory tests on lots of some products before releasing the lots for distribution.

Until we are able to establish our own cGMP manufacturing facility, we expect to continue to rely on third parties for the production of clinical quantities of our product candidates, and expect to rely in the future on third parties for the production of commercial quantities. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production, or distribution, or may require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing.

The FDA may suspend or revoke product license approvals if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program.

FDA has authority to require post-market studies, in certain circumstances, on reduced effectiveness of a biological product and FDA may require labeling changes related to new reduced effectiveness information. Other potential consequences of a failure to maintain regulatory compliance include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- issuance of safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- untitled letters or warning letters;
- imposition of clinical holds on ongoing clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of approved BLAs;
- product seizure or detention, or refusal to permit the import or export of products;
- mandated modification of promotional materials and labeling, and the issuance of corrective information;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs; or
- fines, injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of prescription drug products, including biological products. These regulations include, among other things, standards and regulations for direct-to- consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities and promotional activities involving the internet and social media. Promotional claims about a drug's safety or effectiveness are prohibited before the BLA is approved. Once a BLA is approved, the sponsor can only make those claims relating to safety, efficacy, purity and potency that are consistent with the biological product's approved label. Additionally, promotional materials for prescription drug products must be submitted to the FDA in conjunction with their first use.

In the U.S., healthcare professionals are generally permitted to prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those approved by the FDA. The FDA does not regulate the practice of medicine or healthcare providers' choice of treatments; however, FDA restricts manufacturers' communications of off-label uses. If a company, including any agent of the company or anyone speaking on behalf of the company, is found to have promoted off-label uses, the company may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the DOJ, or the Office of the Inspector General of HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Pediatric trials and exclusivity

Under the Pediatric Research Equity Act of 2003, a BLA (or BLA supplement thereto) must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. A sponsor who is planning to submit a marketing application for a biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan, or PSP, within sixty days of an end of Phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. Generally, development program candidates designated as orphan drugs are exempt from the above requirements. FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials, and/or other clinical development programs.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. The FDA may send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent exclusivity in the U.S. and, if granted for a biologic, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity for all formulations, dosage forms, and indications of the biologic, including the five-year and three-year non-patent and orphan exclusivity. This six-month exclusivity may be granted if a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of FDA-requested pediatric trials are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection covering the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot accept or approve another application relying on the BLA sponsor's data.

Patent term restoration

Depending upon the timing, duration, and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA, plus the time between the submission date and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of the product's approval. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Regulation of diagnostic patient selection tool

We believe that the success of certain of our product candidates may depend, in part, on the development and commercialization of an imaging agent that will serve, where needed, as a patient selection tool. This diagnostic imaging agent is subject to FDA regulation, review, and approval in the same manner as the therapeutic biological products we are seeking to develop and commercialize and are subject to the same risks.

Other regulatory matters

Manufacturing, sales, promotion and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the U.S. in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or HHS, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

European Union/rest of world government regulation

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. The cost of establishing a regulatory compliance system for numerous varying jurisdictions can be very significant. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union and in other jurisdictions, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a clinical trial authorization application must be submitted for each clinical protocol to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Under the EU Clinical Trials Regulation, this is now done through a single application submitted through the Clinical Trials Information System, or CTIS, as described in more detail below.

The requirements and process governing the conduct of clinical trials vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP, the applicable regulatory requirements, and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of a medicinal product under European Union regulatory systems, we must submit a marketing authorization application. The content of the BLA filed in the U.S. is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing product licensing, pricing, and reimbursement vary from country to country.

Countries that are part of the European Union, as well as countries outside of the European Union, have their own governing bodies, requirements, and processes with respect to the approval of biological products. If we 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.

Clinical trial approval in the European Union

In April 2014, the European Union adopted the Clinical Trials Regulation (EU) No 536/2014, which replaced the Clinical Trials Directive 2001/20/EC on January 31, 2022. The Clinical Trials Regulation is directly applicable in all European Union Member States meaning no national implementing legislation in each European Union Member State is required. The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, through the CTIS; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts (Part I contains scientific and medicinal product documentation and Part II contains the national and patient-level documentation). Part I is assessed by a coordinated review by the competent authorities of all European Union Member States in which an application for authorization of a clinical trial has

been submitted (Member States concerned) of a draft report prepared by a reference Member State. Part II is assessed separately by each Member State concerned. Strict deadlines have also been established for the assessment of clinical trial applications.

Marketing authorization procedures in the European Union

Medicines can be authorized in the European Union by using either the centralized authorization procedure or national authorization procedures.

The European Commission implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Economic Area, or the EEA, which is comprised of the Member States of the European Union plus Norway, Iceland, and Lichtenstein. The centralized procedure is administered by the European Medicines Agency, or EMA, and is compulsory for human medicines that are: derived from certain biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV, AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, advanced therapy medicines (gene therapy, somatic cell therapy or tissue-engineered medicines), and officially designated orphan medicines.

For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned contains a new active substance not yet authorized in the European Union, is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the European Union.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use, or the CHMP, is responsible for conducting the initial assessment of a product and for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Clock stops may extend the timeframe of evaluation of a marketing authorization application considerably beyond 210 days. Where the CHMP gives a positive opinion, it provides the opinion together with supporting documentation to the European Commission, who makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops, but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Prior to obtaining a marketing authorization in the European Union, applicants must demonstrate compliance with all measures included in an EMA-approved pediatric investigation plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver, or a deferral for one or more of the measures included in the PIP. The Pediatric Committee of the EMA, or the PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine for children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine for children is not needed or is not appropriate, such as for diseases that only affect the elderly population.

Data and market exclusivity in the European Union

In the European Union, innovative medicinal products approved on the basis of a complete and independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the European Union, during a period of eight years from the date on which the reference product was first authorized in the European Union.

Reform of the regulatory framework in the European Union

The European Commission introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the European Union for all medicines (including those for rare diseases and for children). The European Commission has provided the legislative proposals to the European Parliament and the European Council for their review and approval and, in April 2024, the European Parliament proposed amendments to the legislative proposals. Once the European Commission's legislative proposals are approved (with or without amendment), they will be adopted into European Union law.

The aforementioned European Union rules are generally applicable in the EEA.

Brexit and the Regulatory Framework in the United Kingdom

The United Kingdom, or UK, formally left the European Union on January 31, 2020, and the European Union and the UK have concluded a trade and cooperation agreement, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of cGMP, inspections of manufacturing facilities for medicinal products and cGMP documents issued, but does not provide for wholesale mutual recognition of UK and EU pharmaceutical regulations. At present, Great Britain has implemented European Union legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the European Union regulatory framework currently continues to apply in Northern Ireland). The regulatory regime in Great Britain therefore aligns in many ways with current European Union regulations, however it is likely that these regimes will diverge significantly in the future now that Great Britain's regulatory system is independent from the European Union and the TCA does not provide for mutual recognition of UK and European Union pharmaceutical legislation. However, notwithstanding that there is no wholesale recognition of European Union pharmaceutical legislation under the TCA, under a new international recognition procedure which was put in place by the Medicines and Healthcare products Regulatory Agency, or the MHRA, on January 1, 2024, the MHRA may take into account decisions on the approval of a marketing authorization from the EMA (and certain other regulators) when considering an application for a Great Britain marketing authorization.

On February 27, 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the UK. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide marketing authorization will be granted by the MHRA for all medicinal products to be sold in the UK, enabling products to be sold in a single pack and under a single authorization throughout the UK. The Windsor Framework was approved by the EU-UK Joint Committee on March 24, 2023, so the UK government and the European Union will enact legislative measures to bring it into law. On June 9, 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025.

Pharmaceutical coverage, pricing and reimbursement

In the U.S. and foreign markets, sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement for our products from third-party payors, such as government healthcare programs (e.g., Medicare, Medicaid), managed care organizations, private health insurers, health maintenance organizations, and other organizations. These third-party payors decide which medications they will pay for and will establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and other third-party payors is essential for patients depending on government or commercial insurance to pay for the costs of prescription medications and other medical products.

In the U.S., the principal decisions about reimbursement for new medicines are typically made by the CMS, an agency within the HHS. CMS decides whether and to what extent products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, including government healthcare programs (e.g., Medicare, Medicaid), managed care organizations, private health insurers, health maintenance organizations, and other organizations. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved.

In the U.S., no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party payors are increasingly challenging pharmaceutical prices and examining the medical necessity and cost- effectiveness of medical products and services, in addition to their safety and efficacy. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our

products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. A decision by a third-party payor not to cover a product could reduce utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition.

Further, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and impacted by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the U.S. has increased and could increase the pressure on pharmaceutical 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.

Other U.S. Healthcare Laws

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of drug products for which we obtain marketing approval. Arrangements with third-party payors, healthcare providers and physicians, as well as patients and other third parties, in connection with the clinical research, sales, marketing and promotion of products, once approved, and related activities, may expose a pharmaceutical manufacturer to broadly applicable fraud and abuse and other healthcare laws and regulations. In the U.S., these laws include, without limitation, state and federal anti-kickback, false claims, transparency, consumer protection, and patient data privacy and cybersecurity laws and regulations, including but not limited to those described below:

- The Anti-Kickback Statute, or AKS, makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer or pay any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, that is intended to induce or reward, referrals including the purchase, recommendation, order or prescription of a particular drug for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, patients, and formulary managers on the other. 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. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the AKS is violated. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA.
- The federal civil and criminal false claims laws, including the FCA, impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal or state health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. The FCA also permits a private individual acting as a whistleblower to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. Manufacturers can be held liable under the federal 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, and continue to be, prosecuted under these laws, among other things, for allegedly providing kickbacks to providers or patients or causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus

generally non-reimbursable, uses. Similar to the AKS, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation.

- The Civil Monetary Penalties Law, which covers a variety of conduct, often violations under other laws, and includes penalties for violating the AKS, causing the submission of false claims, and offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program (e.g., public or private) or making any false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Like the AKS, the Patient Protection and Affordable Care Act, or the ACA, amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, also imposes requirements related to the privacy, security and transmission of individually identifiable health information that may apply to many healthcare providers, physicians, and third-party payors with whom we interact.
- The federal Physician Payments Sunshine Act and its implementing regulations, which require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS, under the Open Payments Program, information related to payments or other transfers of value made to physicians (which has the same meaning as under Section 1861(r) of the Social Security Act, which generally includes doctors of medicine, osteopathy, dentists, optometrists, podiatrists and chiropractors who are legally authorized to practice by a state), to certain non-physician providers such as physician assistants and nurse practitioners, and to teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.
- Federal government price reporting laws, which require manufacturers to calculate and report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under governmental healthcare programs.
- Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.
- Analogous state laws and regulations, such as state anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensation and other remuneration and items of value provided to healthcare professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. In addition, commercialization of any drug product outside the U.S. will also likely be subject to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws in the future. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to, on a corporate or individual basis, penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and even imprisonment, any of which could materially adversely affect our ability to operate our business and our financial results. In addition, the cost of implementing sufficient systems, controls, and processes to ensure compliance with all of the aforementioned laws could be significant. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of the company's business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found noncompliant with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct 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. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is

possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights those actions, our business may be impaired.

In the ordinary course of our business, we and the third parties upon which we rely collect, receive, store, or otherwise process personal data, including information we may collect about participants in our clinical trials. Our data processing activities subject us to numerous, evolving data privacy and cybersecurity obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and cybersecurity.

The legislative and regulatory framework for the processing of personal data worldwide is rapidly evolving in a manner that is increasingly stringent and, globally, this legal and regulatory framework is likely to remain uncertain for the foreseeable future. In the U.S., numerous federal, state and local laws and regulations, including federal health information privacy laws, state information security and data breach notification laws, federal consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), state consumer protection and privacy laws, and other similar laws (e.g., wiretapping and communications interception laws) govern the processing of health-related and other personal data.

At the state level, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording individuals certain rights concerning their personal data. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While existing state comprehensive privacy laws exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, a smaller number of states have passed or are considering laws governing the privacy of consumer health data. For example, Washington's My Health My Data Act broadly defines consumer health data, creates a private right of action to allow individuals to sue for violations of the law, imposes stringent consent requirements, and grants consumers certain rights with respect to their health data, including to request deletion of their information. Connecticut and Nevada have also passed similar laws regulating consumer health data. These various data privacy and cybersecurity laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Additionally, to the extent we collect personal information from individuals outside of the United States, through clinical trials or otherwise, we are, or may become, subject to foreign data privacy and security laws, such as the European Union's General Data Protection Regulation 2016/679 (or EU GDPR) and other national data protection legislation in force in relevant EEA Member States, and the EU GDPR as it forms part UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018 (or UK GDPR). Foreign data privacy and cybersecurity laws impose significant and complex compliance obligations on entities that are subject to those laws, as more fully discussed in the section titled "Risk Factors—Risks related to government regulation".

Current and Future U.S. Healthcare Reform Legislation

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new and innovative technologies, such as pharmaceutical products like [^{225}Ac]Ac-AKY-1189. In both the U.S. and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell products profitably.

By way of example, the U.S. and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the ACA, was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; created the Medicare Part D coverage gap discount program, in which manufacturers agree to provide 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price for any approved products.

Since its enactment, there have been, and continue to be, numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and there could be additional amendments to the ACA in the future. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what effect further changes to the ACA would have on our business.

Additionally, there have been several U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient support programs, reduce the costs of drugs under Medicare and reform government program reimbursement

methodologies for drug products. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The IRA includes several provisions that may impact pharmaceutical companies to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries; impose new manufacturer financial liability on all drugs in Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D pricing caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for drug prices that increase faster than inflation; and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. Generally, these government prices can apply as soon as nine years (for small-molecule drugs) or 13 years (for biological products) from their FDA approval and will be capped at a statutory ceiling price that is likely to represent a significant discount from average prices to wholesalers and direct purchasers. The implementation of the IRA is currently subject to ongoing litigation that challenges the constitutionality of the IRA's Medicare drug price negotiation program. The full impact of the IRA on our business and the pharmaceutical and healthcare industry in general is not yet known.

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.

Employees and Human Capital Resources

As of December 31, 2025, we had 79 full-time employees. Of these employees, 67 are engaged in research and development and 12 are engaged in business development, finance, legal, and general management and administration. Our human capital resources objectives include identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Corporate Information

We were originally incorporated under the laws of the State of Delaware in August 2020 under the name HotKnot Therapeutics, Inc. We changed our name to Aktis Oncology, Inc. in April 2021. Our principal executive offices are located at 17 Drydock Avenue, Suite 17-401, Boston, Massachusetts 02210 and our telephone number is (617) 461-4023.

Available Information

We file electronically with the Securities and Exchange Commission, the SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information. Our SEC filings are available to the public over the Internet at the SEC's website at http://www.sec.gov. Our website address is https://www.aktisoncology.com. We make available on our website, under "Investors," free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing these reports with the SEC. The information contained in, or accessible through, our website does not constitute a part of this Annual Report. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors.

You should carefully consider the risks and uncertainties described below, as well as the other information in this Annual Report, including our consolidated financial statements and the related notes appearing elsewhere in this Annual Report and the sections of this Annual Report titled "Special Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" before you make an investment decision in our common stock. The risks described below are not the only risks that we face. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, results of operations and prospects.

Risks related to our limited operating history, financial condition and need for additional capital

We have incurred significant losses since our inception, have no products approved for sale, and we expect to incur losses for the foreseeable future.

Development of radiopharmaceutical product candidates is a highly speculative undertaking and involves a substantial degree of risk. We are still in the early stages of development of our product candidates and our lead product candidate, [^{225}Ac]Ac-AKY-1189, is being evaluated in a Phase 1b clinical trial for locally advanced or metastatic urothelial cancer, or UC, and other Nectin-4 expressing tumors. We have no products licensed for commercial sale and have not generated any revenues from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As such, we have incurred significant losses since inception, and have financed our operations principally through equity financings. We expect that it will be several years, if ever, before we have a commercialized product candidate and generate revenue from sales.

Our net losses for the years ended December 31, 2025 and 2024 were $63.7 million and $44.0 million, respectively. As of December 31, 2025, we had an accumulated deficit of $156.6 million. We anticipate that our expenses and operating losses will increase substantially as we:

- advance our lead product candidate, [^{225}Ac]Ac-AKY-1189 for Nectin-4 expressing tumors, through clinical trials;
- advance our second product candidate, [^{225}Ac]Ac-AKY-2519 for B7-H3 expressing tumors, into clinical trials;
- continue to advance our miniprotein radioconjugate platform;
- acquire or in-license other product candidates, targeting molecules and technologies;
- pursue investigational new drug, or IND,-enabling preclinical studies for our other programs;
- conduct preclinical studies and clinical studies for our other product candidates;
- seek to identify additional product candidates;
- continue to expand partnerships with domestic and international isotope suppliers to create redundancies in our supply chain;
- scale up our supply of ^{225}Ac and other radioisotopes;
- seek regulatory approval of product candidates that successfully complete clinical development;
- obtain, expand, maintain, defend, protect and enforce our intellectual property portfolio;
- continue to expand manufacturing capabilities through additional in-house facilities and expertise, as well as additional third party contractors to enable global commercial scale;
- continue to utilize third parties to manufacture our lead product candidate;
- undertake pre-commercial activities to enhance commercialization prospects for any current or future product candidates that we may seek to obtain regulatory approval for;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- expand our operational, financial, and management systems and increase personnel, including personnel to support our preclinical and clinical development, manufacturing and commercialization efforts; and
- add operational, legal, compliance, financial and management information systems and personnel to support our research, product development and future commercialization efforts, as well as to support our operations as a public company.

Because of the numerous risks and uncertainties associated with the development of radiopharmaceutical therapies, we are unable to accurately predict the timing or amount of increased expenses. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek regulatory approval for, and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. For example, if we are required by the United States Food and Drug Administration, or FDA, or comparable foreign regulatory authorities to perform studies or clinical trials in addition to those we currently anticipate, or if there are any delays in commencing or completing our clinical trials or the development of any product candidates, our expenses could increase and commercial revenue could be further delayed and more uncertain, which will adversely affect our business. We may not be successful in navigating these challenges, which may adversely affect our business, results of operations and prospects.

Our limited operating history may make it difficult for you to evaluate our prospects and likelihood of success.

We have a limited operating history upon which you can evaluate our business and prospects. Since our inception in August 2020, we have devoted substantially all our resources and efforts to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies, in-licensing technology, building out our manufacturing facility and establishing arrangements with third parties for the supply and manufacture of our product candidates and component materials. We have commenced a multi-site Phase 1b clinical trial in the United States to evaluate our lead product candidate, [^{225}Ac]Ac-AKY-1189, for the treatment of locally advanced or metastatic UC and other Nectin-4 expressing tumors. We have not yet demonstrated our ability to successfully complete any clinical trials, obtain regulatory approvals, manufacture a commercial scale product supply, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Such factors include, among other things, the timing of, cost of, and level of investment in, research, development, and commercialization activities, which could vary over time. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

We will require additional funding to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we would be forced to delay, reduce, or eliminate our research and product candidate development programs.

Developing radiopharmaceutical product candidates, including conducting preclinical studies and clinical trials, is a very time-consuming, capital-expensive, and uncertain process that takes years to complete. We have commenced a multi-site Phase 1b clinical trial in the United States to evaluate our lead program, [^{225}Ac]Ac-AKY-1189, for the treatment of locally advanced or metastatic UC and other Nectin-4 expressing tumors and are preparing to commence a Phase 1b clinical trial for [^{225}Ac]Ac-AKY-2519. We are also evaluating multiple current product candidates in preclinical studies. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue the research and development of, advance the preclinical and clinical activities of, and seek regulatory approval for, [^{225}Ac]Ac-AKY-1189 for Nectin-4 expressing tumors from the FDA and other foreign regulatory authorities, as well as our other product candidates. In addition, if we obtain regulatory approval for [^{225}Ac]Ac-AKY-1189 for any Nectin-4 expressing tumor or our other product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of our collaborators. We may also need to raise additional funds sooner if our preclinical and clinical activities take longer than expected, as a result of regulatory approvals or otherwise, or if we choose to pursue additional indications and geographies for any of our product candidates or otherwise expand more rapidly than we presently anticipate.

Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we will be forced to delay, reduce, or eliminate programs, and may be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition, results of operations and prospects.

As of December 31, 2025, we had $226.8 million in cash, cash equivalents and marketable securities. Based on our current business plans, we believe that our existing cash, cash equivalents and marketable securities, together with the net proceeds of approximately $335.3 million from our initial public offering completed in January 2026, will be sufficient to fund our operating expenses and capital expenditure requirements into 2029. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect, requiring us to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to

delay, limit, reduce or terminate clinical trials, our research and development programs or other operations, or lead us to grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, we may seek additional capital opportunistically due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities. See "Management's discussion and analysis of financial condition and results of operations—Liquidity and capital resources."

Our future capital requirements will depend on, and could increase significantly because of many factors including:

- the scope, progress, results and costs related to the clinical development of [^{225}Ac]Ac-AKY-1189 for Nectin-4 expressing tumors;
- the scope, progress, results and costs of planned clinical trials for [^{225}Ac]Ac-AKY-2519 for B7-H3 expressing tumors and our other future product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the cost of advancing and furthering our miniprotein radioconjugate platform;
- the costs of establishing, operating and maintaining our manufacturing facility, or securing other manufacturing arrangements for clinical-supply and commercial production;
- the cost and availability of sufficient supply of ^{225}Ac and other radioisotopes;
- the achievement of milestones or occurrence of other developments that trigger payments by us or our collaborators under any current or future collaboration agreements;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the emergence of competing therapies for oncology indications and other adverse market developments;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, protecting, defending and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory clearances to market [^{225}Ac]Ac-AKY-1189 for any Nectin-4 expressing tumors or any other current or future product candidates.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Any of our current or future license agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements.

We have not generated any revenue to date and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue. We do not expect to generate significant product revenue unless or until we successfully complete clinical development and obtain regulatory approval of, and then successfully commercialize, at least one of our product candidates. Other than [^{225}Ac]Ac-AKY-1189, which is in a Phase 1b clinical trial for the treatment of locally advanced or metastatic UC and other Nectin-4 expressing tumors, all of our product candidates are in the preclinical stages of development and will require additional preclinical studies and clinical development as well as regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We will face significant development risk as our product candidates, including [^{225}Ac]Ac-AKY-1189, advance through clinical development. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely completion of our preclinical studies and our current and future clinical trials, which may be significantly slower or more costly than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- our ability to complete IND-enabling studies and successfully submit IND applications or comparable applications to allow us to initiate clinical trials for any other current or future product candidates;
- whether we are required by the FDA or similar foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA or similar foreign regulatory authorities the safety, potency, purity and acceptable risk-to-benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;

- the timely receipt of necessary marketing approvals from the FDA or similar foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates as potential cancer treatments;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if licensed for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others; and
- our ability to establish, maintain, enforce, protect and defend intellectual property rights in and to our product candidates or any future product candidates.

Many of the factors listed above are beyond our control, and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercialize our product candidates. Even if we are able to commercialize our product candidates, we may not achieve or maintain profitability. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

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 expect our expenses to increase in connection with our planned operations. Unless and until we can generate a substantial amount of revenue from our product candidates, we expect to finance our future cash needs through public or private equity offerings, debt financings, collaborations, licensing arrangements or other sources, or any combination of the foregoing. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. Disruptions in the financial markets in general may make equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs.

To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, your ownership interest may be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming shares or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise additional funds through collaborations, strategic alliances, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we would 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. Any additional fundraising efforts we undertake may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

Risks related to our business and development of our product candidates

We are early in our development efforts. If we are unable to develop, and commercialize, any of our current or future product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts. The success of our business depends upon our ability to identify, develop, and commercialize targeted radiopharmaceuticals across a range of oncology indications. [^{225}Ac]Ac-AKY-1189, our most advanced product candidate, is in a Phase 1b clinical trial for the treatment of locally advanced or metastatic UC and other Nectin-4 expressing tumors. Commencing clinical trials for our current or future product candidates in the United States is subject to clearance by the FDA of an IND application and finalizing the trial design based on discussions with the FDA. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of our planned future clinical trials may be delayed or we may be unsuccessful obtaining clearance to proceed into clinical development. In addition, clinical trials conducted in one country, may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to conditions imposed by the FDA, and there can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not

accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our product candidates.

The success of our product candidates will depend on several factors, including the following:

- successful completion of clinical trials;
- effective INDs or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for any product candidates we may develop;
- successful completion of planned preclinical studies and initiation of clinical trials for our other product candidates;
- successful patient enrollment in, and completion of, clinical trials;
- the ability to successfully develop [^{225}Ac]Ac-AKY-1189 for any Nectin-4 expressing tumors and [^{225}Ac]Ac-AKY-2519 for any B7-H3 expressing tumors;
- the ability to successfully develop additional product candidates;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- timely receipt of approvals for product candidates from applicable regulatory authorities;
- the extent of any required post-regulatory approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- sourcing clinical and, if approved for commercial sale, commercial supplies for the radioisotopes used to manufacture our product candidates;
- securing reliable transport for our product candidates given that isotope stability times are limited once a molecule has been bound;
- successfully establishing and operating our manufacturing facility;
- the ability of dosimetry and imaging assessments to demonstrate sufficient tumor uptake of imaging radioisotopes conjugated to our miniproteins;
- making and maintaining arrangements with third-party manufacturers for both clinical and commercial supplies of our product candidates;
- establishing sales, marketing and distribution capabilities and successfully launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other cancer therapies;
- educating medical personnel regarding the potential side effect profile of our product candidates;
- facilitating patient access to the facilities able to administer our product candidates, if approved;
- obtaining and maintaining third-party coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of our products following regulatory approval.

If we do not achieve one or more of these factors in a timely manner, or at all, we could experience significant delays or be unable to successfully commercialize our product candidates, which would materially harm our business.

Our business is highly dependent on our lead product candidate, [^{225}Ac]Ac-AKY-1189, for the treatment of Nectin-4 expressing tumors. We must complete clinical trials before we can seek regulatory approval and begin commercialization of [^{225}Ac]Ac-AKY-1189. If we are unable to obtain regulatory approval for, and successfully commercialize, [^{225}Ac]Ac-AKY-1189, our business may be materially harmed, and such failure may affect our other current or future product candidates.

The process for obtaining marketing approval for any product candidate, including [^{225}Ac]Ac-AKY-1189, is very long and risky and there will be significant challenges for us to address to obtain marketing approval as planned, if at all. There is no guarantee that the results obtained in our ongoing and planned clinical trials of [^{225}Ac]Ac-AKY-1189 will be sufficient to obtain regulatory approval. Furthermore, success in an early-stage trial does not necessarily mean a later stage trial will be successful. In addition, because our other product candidates are based on similar technology of our lead product candidate, if [^{225}Ac]Ac-AKY-1189

encounters safety or efficacy problems, manufacturing or supply interruptions, developmental delays, regulatory issues, or other problems, our development plans and business related to other product candidates could be significantly harmed.

Preclinical and clinical development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If preclinical studies or clinical trials of a product candidate are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize [^{225}Ac]Ac-AKY-1189, [^{225}Ac]Ac-AKY-2519 or any of our future product candidates on a timely basis or at all.

We, and any future collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities, such as the European Medicines Agency, or EMA, impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We, and any future collaborators, must complete additional preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

For our current and future product candidates, we may not be able to file IND applications, or similar applications outside the United States, on the timelines we expect. For example, we may experience supply or manufacturing delays or other delays with IND-enabling, or equivalent foreign preclinical studies. Moreover, we cannot be sure that submission of an IND application, or similar applications outside the United States, will result in the FDA, or comparable foreign regulatory authorities, allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND application, or similar applications outside the United States, we cannot guarantee that such regulatory authorities will not change their requirements in the future. We also cannot predict that approval of an IND application or similar application by the FDA or comparable foreign regulatory authority will result in approval of similar applications to conduct clinical trials. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or similar approvals outside the United States. We do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time, or be completed on schedule, if at all.

Clinical trials can be delayed, suspended, or terminated for a variety of reasons, including the following:

- delays in or failure to obtain regulatory authorization to commence a clinical trial;
- delays in or failure to obtain institutional review board, or IRB, approval at each site or national competent authority approvals including positive ethics committee opinions;
- delays in or failure to reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- difficulty in recruiting clinical trial investigators of appropriate competencies and experience;
- delays in establishing the appropriate dosage levels in clinical trials;
- delays in or failure to recruit and enroll suitable patients to participate in a clinical trial, as well as inclusion and exclusion criteria and patients' prior lines of therapy and treatment;
- lower than anticipated retention rates of patients in clinical trials;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a clinical trial;
- delays adding new investigators or clinical trial sites;
- our third-party research contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- changes in regulatory requirements, policies, and guidelines;
- our ability to obtain sufficient radioactive supplies, and to manufacture and deliver sufficient quantities of a product candidate for use in clinical trials;
- the quality or stability of a product candidate falling below acceptable standards;
- changes in the treatment landscape for our target indications in oncology that may make any of our current or future product candidates no longer relevant;
- third-party actions claiming infringement by our product candidates in clinical trials outside the United States and obtaining injunctions interfering with our progress; and

- business interruptions resulting from geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods, and wildfires, or disease.

Moreover, clinical trials must be conducted in accordance with the FDA and comparable foreign regulatory authorities' legal requirements, regulations, and guidelines, and are subject to oversight by regulatory authorities and IRBs or ethics committees at the medical institutions where the clinical trials are conducted.

Safety or tolerability concerns could cause us or regulatory authorities, as applicable, to suspend or terminate a clinical trial if it is found that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unfavorable characteristics of the product candidate, or if such undesirable effects or risks are found to be caused by a chemically or mechanistically similar therapeutic or therapeutic candidate. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such trials are being conducted, by the data review committee or data safety monitoring board for such trial or by the FDA, or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial.

In 2021, the FDA launched Project Optimus as an initiative to reform the dose optimization and dose selection paradigm in oncology drug development with the goal of advancing an oncology dose-finding and dose optimization paradigm that emphasizes dose selections that maximize efficacy as well as safety and tolerability. In support of this initiative, the FDA may request sponsors of oncology product candidates to conduct dose optimization studies before permitting sponsors to initiate a pivotal study. In early 2023, the FDA issued a draft guidance intended to assist sponsors in identifying the optimal dosages for these products during clinical development and prior to applying for approval for a new indication and usage as well as another draft guidance intended to provide recommendations to sponsors of anticancer drugs or biological products on considerations for designing trials intended to support accelerated approval. In August 2004, the FDA issued final guidance on optimizing the dosage of oncology drugs and biologics, which noted that while the guidance did not contain specific recommendations for radiopharmaceuticals, some of the recommendations in the guidance may be applicable to these products. If we are required to conduct dose optimizing studies, such studies may delay our product development activities.

If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for Diversity Action Plans, or DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance. On January 27, 2025, in response to an Executive Order issued on January 21, 2025, on Diversity, Equity and Inclusion programs, the FDA removed this draft guidance from its website. This action raises questions about the applicability of statutory obligations to submit DAPs and the agency's current thinking on best practices for clinical development.

Furthermore, even if we are able to complete our manufacturing facility, we will continue to rely on contract manufacturing organizations, or CMOs, and contract development and manufacturing organization, or CDMOs, for the proper and timely manufacturing of our product candidates in accordance with cGMP requirements. We also intend to continue to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials in compliance with good clinical practice, or GCP, requirements. While we have agreements governing their committed activities, we will have limited influence over their actual performance. To the extent our CMOs fail to comply with cGMP or to perform their manufacturing obligations in a timely manner, or our CROs fail to enroll participants for our clinical trials, fail to conduct the study in accordance with GCP, or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, or both, which may harm our business.

Moreover, any clinical trials that we may conduct in countries outside the United States may subject us to further delays and expenses because of increased shipment and distribution costs, additional regulatory requirements, and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening, and medical care. The FDA may decline to accept the data we obtain from these clinical studies in support of an IND application or a biologics license application, or BLA, in the United States, which may require us to repeat or conduct additional preclinical studies or clinical trials that we did not anticipate in the United States, and therefore we may be unable to commercialize our current or future product candidates, on a timely basis or at all in the United States. Foreign regulatory authorities may also decline to accept data obtained from clinical studies conducted in the United States in support of a related marketing authorization application which may lead to similar risks in countries outside the United States.

If we experience delays in the completion of, or termination of, any clinical trial, the commercial prospects of [^{225}Ac]Ac-AKY-1189 for Nectin-4 expressing tumors, or our other product candidates will be harmed, and our ability to generate revenue from sales

of any products will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our development and approval process, and jeopardize our ability to commence sales and generate revenue. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates and impair our ability to commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Our clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of [^{225}Ac]Ac-AKY-1189, [^{225}Ac]Ac-AKY-2519, or any of our future product candidates, which would prevent or delay or limit the scope of regulatory approval and commercialization.

To obtain the requisite regulatory approvals to market and sell [^{225}Ac]Ac-AKY-1189, [^{225}Ac]Ac-AKY-2519, or any of our future product candidates, we must demonstrate through clinical trials that such product candidates are safe and effective for use in each targeted indication. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. Unforeseen side effects could arise either during clinical development or, if such side effects are more rare, after our products have been approved by regulatory authorities and the approved product has been marketed, resulting in the exposure of additional patients than if such side effect had arisen during a clinical trial. Furthermore, the results of our Phase 1b clinical trial may not demonstrate the clinical utility of [^{225}Ac]Ac-AKY-1189, or reveal an unacceptable safety profile. Additionally, assessments of the long-term safety of targeted alpha-emitting isotope therapies in humans have been limited, and there may be long-term effects from treatment with [^{225}Ac]Ac-AKY-1189 or any of our other current or future product candidates that we cannot predict at this time. Further, we may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing.

Clinical trials that we conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market [^{225}Ac]Ac-AKY-1189, [^{225}Ac]Ac-AKY-2519 or any of our future product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols, and the rate of dropout among clinical trial participants. Additionally, our Phase 1b clinical trial for [^{225}Ac]Ac-AKY-1189 is, and we expect future trials of our product candidates to be, open-label trials, meaning both the patient and investigator know whether the patient is receiving the investigational product candidate. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect, as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in an open-label trial would not be replicated in a controlled trial. Moreover, if unacceptable toxicities, undesirable side effects or adverse product-product interactions arise in the development of our product candidates alone or in combination with other therapies, we could suspend or terminate or trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials, deny approval of the product candidate for any or all targeted indications or require a more restrictive label. If the results of our clinical trials are inconclusive with respect to the efficacy of product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, if there are safety concerns associated with our product candidates, or if the results observed cannot be replicated, we may be delayed in obtaining regulatory approval, if at all. Additionally, any safety concerns observed in our clinical trials, or in the clinical experience of others using our product candidates in "compassionate use" scenarios outside of the United States, or investigating similar products or modalities could impact our prospects for regulatory approval in those and other indications.

Even if the trials are successfully completed, clinical data is often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit any future BLA or comparable foreign application. We cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as having efficacy even if positive results are observed in clinical trials. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the clinical trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a regulatory application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional development work. Even if regulatory approval is secured for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential.

Our approach to the discovery and development of product candidates using our miniprotein radioconjugate platform represents a novel approach to radiation therapy, which may create significant and potentially unpredictable challenges for us.

Our future success depends on leveraging our miniprotein radioconjugate platform to successfully develop product candidates which are designed to treat advanced solid tumors, utilizing a novel approach to directed-radiation therapy. There are currently few approved radiopharmaceutical therapeutic products. In addition, there has been limited historical clinical trial experience, generally, for the development of radiopharmaceutical therapeutics. As a result, the design and conduct of clinical trials for these product candidates is uncertain and subject to increased risk.

While external beam radiation as a therapy for cancers has existed for decades, oncology treatment using systemic delivery of targeted radiopharmaceuticals in general, and alpha emitting isotopes specifically, is relatively new. Only one alpha emitting isotope therapy, Xofigo, which uses the isotope radium-223, or ^{223}radium, has been approved in the United States or the European Union, or EU, and only a limited number of clinical trials of products based on alpha emitting isotope therapies have commenced. Approved therapies containing beta emitting isotopes have also been limited. As such, it is difficult to accurately predict the developmental challenges we may incur for our product candidates as they proceed through discovery or identification, preclinical studies, and clinical trials. In addition, beyond the limited universe of patients treated with Xofigo, assessments of the long-term safety of targeted alpha emitting isotope therapies in humans have been limited, and there may be long-term effects from treatment with our product candidates that we cannot predict at this time.

It is difficult for us to predict the time and cost of the development of our product candidates, and we cannot predict whether the application of our technology, or any similar or competitive technologies, will result in the identification, development, and regulatory approval of any products. There can be no assurance that any development problems we experience in the future related to our technology or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved at all. Any of these factors may prevent us from completing our preclinical studies and clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

Our product candidates may cause adverse events, undesirable side effects or have other properties that could halt their preclinical or clinical development, prevent, delay, or cause the withdrawal of their regulatory approval, limit their commercial potential, or result in significant negative consequences, including death of patients. If any of our product candidates receive marketing approval and we, or others, later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability, or that of any potential future collaborators, to market the product could be compromised.

As with most biological products, use of our product candidates could be associated with undesirable side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials.

Treatment-related undesirable side effects or adverse events could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or could result in potential product liability claims. In addition, these side effects may not be appropriately or timely recognized or managed by the treating medical staff, particularly outside of the research institutions that collaborate with us. We have, and will need to continue to, educate and train medical personnel using our product candidates to understand their side effect profiles, for our ongoing Phase 1b clinical trial of [^{225}Ac]Ac-AKY-1189 and any future clinical trials, and upon any commercialization of any product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in adverse events to patients, including death. Any of these occurrences may materially and adversely harm our business, financial condition, results of operations and prospects.

Clinical trials of our product candidates must be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any potential future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives marketing approval and we, or others, discover that it is less effective than previously believed or causes undesirable side effects that were not previously identified, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product, seize the product, or seek an injunction against its manufacture or distribution;
- we, or any future collaborators, may be required to recall the product, change the way such product is administered to patients or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication, or impose distribution or use restrictions;
- we, or any future collaborators, may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we, or any future collaborators, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects, and could adversely impact our financial condition, results of operations or the market price of our common shares.

Results of preclinical studies, dosimetry assessments, and early-stage clinical trials may not be predictive of the results of future preclinical studies or clinical trials.

Success in preclinical studies does not ensure that later preclinical studies or clinical trials will be successful. Several companies in the biotechnology industry have suffered significant setbacks in clinical trials, even after positive results in preclinical and earlier clinical trials. These setbacks have been caused by, among other things, negative preclinical findings identified after clinical trials have already commenced and safety or efficacy observations made in clinical trials, including previously unanticipated adverse events. We cannot predict if the FDA or comparable foreign regulatory authority will consider the data from our future preclinical studies sufficient to support approval of an IND application or similar application. In addition, preclinical data is often susceptible to varying interpretations and analyses, which could require us to repeat or conduct additional preclinical studies. Notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies, may not be predictive of the results of outcomes in subsequent clinical trials on human subjects. Product candidates in clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies.

The dosimetry assessments conducted using radioconjugates of our product candidates used may not be predictive of the anticancer effect or safety profile of our product candidates and we have had limited control and input over the conduct of this assessment and the reported results. The ability of our miniproteins to localize on tumors does not ensure that our product candidates will be successful at eradicating the tumor with an acceptable risk and safety profile, if at all. Likewise, the results of any early-stage clinical trials may not be predictive of the results of the later-stage clinical trials, which tend to enroll substantially larger numbers of patients. The preliminary results of clinical trials with smaller sample sizes can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. We plan to enroll larger patient populations in later trials of [^{225}Ac]Ac-AKY-1189. With significantly more patients in future phases of the trial, we may not achieve statistically significant results or the same level of statistical significance, if any, that are observed in any earlier trials. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. In addition, results in one indication may also not be predictive of results to be expected for the same product candidate in another indication.

If we fail to receive positive results in preclinical studies or early-stage clinical trials, or those results are not replicated in later-stage clinical trials of any product candidate or across indications for that product candidate, the development timeline and regulatory approval and commercialization prospects for that product candidate, and, correspondingly, our business, financial condition, results of operations and prospects, would be harmed.

The administration of AKY-1189 to patients in South Africa pursuant to Section 21 of the Medicines and Related Substances Act, or MRSA, as authorized by the South African Health Products Regulatory Authority, or SAPHRA, was conducted by a third-party physician. We had limited control and input with respect to the collection of the data from the patients in South Africa conducted pursuant to Section 21 of the MRSA and the manner in which it was conducted and will have limited control with respect to the human imaging data being gathered pursuant to Section 21 of the MSRA. We have relied on the results of the assessment to inform our development of [^{225}Ac]Ac-AKY-1189, and these results may turn out to be incorrect or unreliable. Similarly, we will be relying on the investigator to conduct the human imaging studies in accordance with the applicable protocol, legal, regulatory and scientific standards, and accurately report the results and correctly collect the data. If these results prove to be unreliable, the development of [^{225}Ac]Ac-AKY-1189 may be adversely affected.

Interim, topline, or preliminary data from our preclinical studies and clinical trials that we announce or publish from time to time may change as more patient data becomes available or as we make changes to our manufacturing processes and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline, or preliminary data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the study or trial. Preliminary or interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data becomes available. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to evaluate all data fully and carefully. Further, modifications or improvements to our manufacturing processes for a therapy may result in changes to the characteristics or behavior of the product candidate that could cause our future product candidates to perform differently and affect the results of our ongoing clinical trials. As a result, other current or the topline results that we report may differ from future results of the same preclinical studies or clinical trials, or different conclusions or considerations may qualify such topline results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially

different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

Adverse differences between preliminary or interim data and final data could significantly harm our business, financial condition, results of operations and prospects. Additionally, disclosure of preliminary or interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate, and our company in general. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our current or future product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Due to the radioactive nature of our product candidates, once manufactured, our product candidates will have time-limited stability, and as a result, we may encounter difficulties with fulfilment and logistics.

[^{225}Ac]Ac-AKY-1189 is designed to provide at least four days of stability following radiolabeling, meaning that the patient must intravenously receive our product candidate within four days of its radiolabeling. We anticipate that our future products candidates utilizing ^{225}Ac, including [^{225}Ac]Ac-AKY-2519, will have similar, limited stable life-span. As such, our product candidates must be manufactured on an as-needed basis, and shipped almost immediately thereafter. Because our product candidates, including [^{225}Ac]Ac-AKY-1189, cannot be "stock-piled" and stored for even a small number of days ahead of shipment, we or any third-party manufacturer must be able to manufacture our product candidates on a rolling basis, and any delays, could result in an immediate and substantial impact on our ability to deliver the product candidate to patients. Any significant delays in delivering product candidates to patients could damage our reputation and result in deviations from our clinical trial protocols, which in turn could affect our ability to advance the clinical development of our product candidates on a timely basis, or at all.

In addition, once manufactured, our product candidates must be quickly and safely transported to the applicable clinical trial site. As we scale our operations and enroll larger clinical trials, and prepare for potential commercialization, we will need to scale our shipping abilities. Labor disputes, government restrictions, work stoppages, pandemics, derailments, damage or loss events, adverse weather conditions, other events beyond our control could interrupt or delay transportation, which could result in the loss or damage of our product candidates. Although, we carry insurance to cover material loss or damage to supplies in transit, any insurance policy claims awarded to us may be insufficient to cover our losses or damages.

We depend on enrollment and retention of patients in our clinical trials. If we experience delays or difficulties enrolling or retaining patients in our clinical trials, our research and development efforts and business, financial condition, results of operations and prospects could be materially adversely affected.

Successful and timely completion of clinical trials will require that we enroll and retain a sufficient number of patient candidates. Any clinical trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal, or adverse events. These types of developments could cause us to delay the trial or halt further development.

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. In addition, in the future, we may evaluate our product candidates as first-in-line treatments for which there are other approved treatment alternatives, which may present enrollment challenges. Because the number of qualified clinical investigators and clinical trial sites capable of administering radiopharmaceutical therapies is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Enrollment may also depend in part on the medical community and public's perception of our product candidates or those of our competitors. Adverse events in our preclinical studies or clinical trials or those of our competitors or of academic researchers or other clinicians utilizing our product candidates under "compassionate use" pathways outside the United States, or similar technologies, even if not ultimately attributable to product candidates we may discover and develop, and the resulting publicity could result in unfavorable public perception and adversely impact our ability to enroll clinical trials.

Delays in the completion of any clinical trial of [^{225}Ac]Ac-AKY-1189 for Nectin-4 expressing tumors or our other current or future product candidates will increase our costs, slow down the development and approval process, and delay or potentially jeopardize our ability to commence sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of [^{225}Ac]Ac-AKY-1189 or any other current or future product candidates.

The commercial success of [^{225}Ac]Ac-AKY-1189, or any of our other current or future products, if approved, will depend upon public perception of radiopharmaceuticals and the degree of their market acceptance by physicians, patients, healthcare payors and others in the medical community.

Adverse events in clinical trials of our product candidates, or in clinical trials or other studies conducted by others involving similar products, which may include the same radioisotopes as our product candidates, and the resulting negative publicity, as well as any other adverse events in the field of radiopharmaceuticals that may occur in the future, could result in a decrease in demand for [^{225}Ac]Ac-AKY-1189 for any approved indication or any future product candidates that we may develop. If public perception is influenced by claims that radiopharmaceuticals or specific therapies within radiopharmaceuticals are unsafe, [^{225}Ac]Ac-AKY-1189 or any other current or future product candidates may not be accepted by the general public or the medical community.

In particular, the commercial success of our products, if approved, will depend upon, among other things, these products gaining and maintaining acceptance by physicians, patients, third-party payors, and other members of the medical community as efficacious and cost-effective alternatives to competing products and treatments. Even if [^{225}Ac]Ac-AKY-1189, or any other product candidates we develop receive marketing approval by the FDA or other foreign regulatory authority, they may not achieve the level of commercial acceptance and sales experienced by approved beta-emitting therapies, Pluvicto and Lutathera. If any of our products, once approved, do not achieve and maintain an adequate level of acceptance, we may not generate material sales or be able to successfully commercialize such product.

The degree of market acceptance of our candidates products, if approved, will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects in general, and relative to other treatments;
- publicity concerning our products or competing products and treatments;
- the relative convenience and ease of administration of our products and product candidates, which may require coordination amongst multiple physicians across disciplines for administration;
- availability, relative cost and relative efficacy of alternative and competing treatments;
- the ability to offer our products for sale at competitive prices;
- the willingness of the target patient population to try therapies and of physicians to prescribe these products;
- the strength of marketing and distribution support; and
- the sufficiency of coverage or reimbursement by third parties.

We may develop [^{225}Ac]Ac-AKY-1189, and potentially future product candidates, in combination with other therapies, which exposes us to additional risks.

We may develop [^{225}Ac]Ac-AKY-1189, and may develop future product candidates, for use in combination with one or more currently approved cancer therapies. Even if any product candidate we develop was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop any of our product candidates for use in combination with other products or for indications other than cancer. This could result in our own products being removed from the market or being less successful commercially.

We may also evaluate [^{225}Ac]Ac-AKY-1189 or any other current or future product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA or similar foreign regulatory authorities. We will not be able to market and sell [^{225}Ac]Ac-AKY-1189 or any product candidate we develop in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA or similar foreign regulatory authorities do not approve these other products or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the products we choose to evaluate in combination with [^{225}Ac]Ac-AKY-1189 or any product candidate we develop, we may be unable to obtain approval of or market [^{225}Ac]Ac-AKY-1189 or any other current or future product candidate we develop.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

A key element of our strategy is to apply our development pipeline to address a broad array of cancer targets and new therapeutic areas. The therapeutic discovery activities that we are conducting may not be successful in identifying product candidates that are useful in treating targets in oncology. Our research programs may be unsuccessful in identifying potential

product candidates, or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive regulatory approval.

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms, and product candidates that we identify for specific indications. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms, and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may need to relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

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

The development and commercialization of new radiopharmaceutical products is highly competitive. We face and will continue to face competition from third parties that use radioisotopes and from companies focused on more traditional therapeutic modalities. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization of new products.

We consider our most direct competitors to be companies developing targeted alpha-based radiopharmaceuticals for the treatment of cancer. There are several companies developing targeted alpha-based radiopharmaceuticals for the treatment of cancer, including Abdera Therapeutics, Actinium Pharmaceuticals, Inc., Alpha9 Oncology, Inc., Artbio AS, Bayer AG, Convergent Therapeutics, Fusion Pharmaceuticals Inc. (acquired by AstraZeneca), Johnson & Johnson, Mariana Oncology, Inc. (acquired by Novartis AG), Perspective Therapeutics, POINT Biopharma Global Inc. (acquired by Eli Lilly), RadioMedix, Inc., RayzeBio, Inc. (acquired by Bristol Myers Squibb) and Telix Pharmaceuticals Limited. These companies are targeting a wide range of solid and hematologic malignancies using various alpha emitting isotopes, including ^{223}radium, lead-212 and ^{225}Ac. The first and only approved alpha particle-based therapy is Bayer's Xofigo (^{223}radium) which is a salt of radium that cannot easily and robustly be attached to a targeting molecule, but naturally localizes to regions where cancer cells are infiltrating bone. Xofigo was approved in 2013 for the treatment of prostate cancer with symptomatic bone metastases.

There are several companies with approved beta-emitting radiopharmaceuticals, including Lantheus Holdings, Novartis, Bayer, Sirtex, Boston Scientific and Q BioMed Inc. and other companies developing beta-emitting radiopharmaceuticals, including POINT Biopharma Global, ITM Isotope Technologies Munich SE, Y-Mabs and Telix Pharmaceuticals Limited. The beta emitting isotopes used by these companies include iodine-131, lutetium-177, strontium-89 and yttrium-90. A recently approved beta particle-based radiopharmaceutical is Novartis' Pluvicto, which was approved by the FDA in 2022 for the treatment of patients with metastatic prostate cancer.

Our competitors will also include companies that are or will be developing other treatment methods as well as therapies for the same indications in oncology that we are targeting. In addition to the competitors we face in developing radiopharmaceuticals, we will also face competition in the indications we expect to pursue. In order to compete effectively with these existing therapies, we will need to demonstrate that our therapies are favorable to existing therapeutics and obtain comparable coverage and reimbursement for our product candidates.

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

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 or our collaborators may develop. Our competitors also may obtain FDA or other foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. Even if the product candidates we may develop in the future achieve regulatory approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Moreover, technological advances or products developed by our competitors may render our technologies or product candidates we may develop in the future obsolete, less competitive, or not economical. The key competitive factors affecting the success of [^{225}Ac]Ac-AKY-1189 and our other current and future product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

The market opportunities for our product candidates may be smaller than we anticipated or may be limited to those patients who are ineligible for or have failed prior treatments. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Our current and future target patient populations are based on our beliefs and estimates regarding the incidence or prevalence of certain types of cancers that may be addressable by our product candidates, which is derived from a variety of sources, including scientific literature and surveys of clinics. Our projections may prove to be incorrect and the number of potential patients may turn out to be lower than expected. Even if we obtain significant market share for our product candidates, because the potential target populations could be small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use of our product candidates for front-line and second-line therapy.

We expect to initially seek approval of some of our product candidates, including [^{225}Ac]Ac-AKY-1189 and [^{225}Ac]Ac-AKY-2519, as second-or third-line therapies for patients who have failed other approved treatments.

Subsequently, for those product candidates that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second-line therapy and potentially as a front-line therapy, but there is no guarantee that our product candidates, even if approved for third-line therapy, would be approved for second-line or front-line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for second-line or front-line therapy.

Our company has never commercialized a product candidate and may experience delays or unexpected difficulties in obtaining regulatory approval for our current and future product candidates.

Our company has never obtained regulatory approval for, or commercialized, a product. It is possible that the FDA may refuse to accept any or all of our planned BLAs for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any product candidates. If the FDA does not approve any of our planned BLAs, it may require that we conduct additional costly clinical trials, preclinical studies or manufacturing validation studies before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any BLA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any BLA or other application that we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for our applications in foreign jurisdictions.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved for commercial sale, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable to, or decide not to, establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, if licensed. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas for which we are able to obtain regulatory approval.

We may become exposed to costly and damaging liability claims, either when testing [^{225}Ac]Ac-AKY-1189 or our other current or future product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. We currently have no products that have been approved for commercial sale, the use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims, including third-party claims against any of our collaboration partners, some of which we could be contractually obligated to indemnify. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. Any claims against us, regardless of their merit, could be difficult and

costly to defend and could materially adversely affect the market for [^{225}Ac]Ac-AKY-1189 or our other current or future product candidates or any prospects for commercialization.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a product, even after regulatory approval, may exhibit unforeseen side effects. If [^{225}Ac]Ac-AKY-1189 or any of our other current or future product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use [^{225}Ac]Ac-AKY-1189 or our other current or future product candidates.

Even successful defense against product liability claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for [^{225}Ac]Ac-AKY-1189 or any of our other current or future product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- and a decline in our share price.

Although we maintain product liability insurance in the United States, and in other jurisdictions where we have ongoing clinical trials, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain regulatory approval for [^{225}Ac]Ac-AKY-1189 or any of our other current or future product candidates. However, we may be unable to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims, and our business operations could be impaired.

We are party to multiple license and collaboration agreements with significant payment obligations that are contingent upon the occurrence of future events, the timing and likelihood of which are difficult to predict. If we fail to comply with our obligations under these license and collaboration agreements, we could lose rights that are important to our business.

Under our license and collaboration agreements, we have payment obligations that are contingent upon future events, such as the achievement of specified development, regulatory and commercial milestones, and in some cases, we are required to make royalty payments in connection with the sales of products developed under those agreements. Although we could be required to make substantial milestone payments under our license and collaboration agreements, we are currently unable to estimate the timing or likelihood of achieving the milestones or making future sales. For further discussion of our obligations under these agreements, see "Business—License and collaboration agreements."

We may be unable to meet our obligations as they become due, especially in the event that multiple milestones are achieved in a short amount of time. If we are unable to meet our obligations when due, it may result in the delay or termination of the research, development or commercialization of the relevant product candidate, and may result in costly litigation or arbitration that diverts management attention and resources away from our day-to-day activities, which may adversely affect our business, financial condition, results of operations and prospects.

Risks related to government regulation

The development and commercialization of pharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming, and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for [^{225}Ac]Ac-AKY-1189 or any other current or future product candidates, on a timely basis if at all, our business will be substantially harmed.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND application and finalizing the trial design based on discussions with the FDA. Even after we receive and incorporate guidance from the FDA, the FDA could

disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials, delay the enrollment of our clinical trials, abandon our clinical development plans or meet stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the EU.

Furthermore, we have not previously submitted a BLA to the FDA or similar marketing applications to similar foreign regulatory authorities. An BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety, purity and potency for each desired indication. The BLA must also include significant information regarding the manufacturing controls for the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval.

A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls. Outside the United States, many comparable foreign regulatory authorities employ similar approval processes.

[^{225}Ac]Ac-AKY-1189 and any of our current or future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that the product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of BLA or other submission or to obtain regulatory approval in the United States or elsewhere, or regulatory authorities may not accept a submission due to, among other reasons, the content or formatting of the submission;
- the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities or those of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of clinical trial results, may result in our failing to obtain regulatory approval to market [^{225}Ac]Ac-AKY-1189 or any other current or future product candidates, which would significantly harm our business, financial condition, results of operations and prospects. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be obtained for [^{225}Ac]Ac-AKY-1189 or any other current or future product candidates. For example, regulatory authorities in various jurisdictions may have differing requirements for, interpretations of and opinions on our preclinical and clinical data. As a result, we may be required to conduct additional preclinical studies, alter our proposed clinical trial designs, or conduct additional clinical trials to satisfy the regulatory authorities in each of the jurisdictions in which we hope to conduct clinical trials and develop and market our products, if approved. Further, even if we believe the data collected from clinical trials of [^{225}Ac]Ac-AKY-1189 or our other current or future product candidates is promising, such data may not be sufficient to support approval by the FDA or any comparable foreign regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve [^{225}Ac]Ac-AKY-1189 or any other current or future product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for [^{225}Ac]Ac-AKY-1189 or any other current or future product candidates.

We may seek orphan drug designation for the product candidates we develop, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

As part of our business strategy, we may seek orphan drug designation for the product candidates we develop, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs and biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug or biologic as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition, which is defined as a patient

population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Commission grants orphan drug designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an orphan drug designation application. Orphan drug designation is intended to promote the development of drugs and biologics that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs and biologics intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug or biologic in Europe would be sufficient to justify the necessary investment in developing the drug or biologic. In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

Generally, if a drug or biologic with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug or biologic is entitled to a period of marketing exclusivity, which precludes the EMA, or the FDA from approving another marketing application for the same drug and for the same indication during the period of exclusivity, except in limited circumstances. The applicable period is seven years in the United States and 10 years in Europe. The European exclusivity period can be reduced to six years if a drug or biologic no longer meets the criteria for orphan drug designation or if the drug or biologic is sufficiently profitable such that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect such product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug or biologic is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug or biologic to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our current and any future product candidates, we may never receive such designations. Even if we do receive such designation, there is no guarantee that we will enjoy the benefits of that designation.

We may seek one or more designations or expedited programs for one or more of our product candidates, but we might not receive such designations or be allowed to proceed on expedited program pathways, and even if we do and proceed on such expedited program pathways in the future, such designations or expedited programs may not lead to a faster development or regulatory review or approval process, and each designation does not increase the likelihood that any of our product candidates will receive marketing approval in the United States.

We have received fast track designation for [^{225}Ac]Ac-AKY-1189 for the treatment of adult patients with locally advanced or metastatic UC who had progressed on or after prior systemic therapies and may seek fast track designation for certain of our other product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data for the drug demonstrates the potential to address an unmet medical need for such a condition, the drug sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it for any of our other product candidates. Even with fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA.

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

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

Even if [^{225}Ac]Ac-AKY-1189 or any of our other current or future product candidates obtains regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, [^{225}Ac]Ac-AKY-1189 or any of our other current or future product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

If the FDA or a comparable foreign regulatory authority approves [^{225}Ac]Ac-AKY-1189 for any Nectin-4 expressing tumor or any of our other current or future product candidates, the manufacturing facilities and processes, testing, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we or our partners receive a product candidate may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our CMOs will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any approved regulatory application. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, quality control, and distribution.

If there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include issuing warning letters or untitled letters, imposing fines on us, imposing restrictions on the product or its manufacture, and requiring us to recall or remove the product from the market. The regulators could also suspend any of our preclinical studies and clinical trials or suspend or withdraw our regulatory approvals, requiring us to conduct additional clinical trials, change our product labeling, or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition, results of operations and prospects.

In addition, if we have any product candidate approved, our product labeling, advertising, and promotion will be subject to regulatory requirements and continuing regulatory review. In the United States, the FDA and the Federal Trade Commission, or the FTC, strictly regulate the promotional claims that may be made about pharmaceutical products to ensure that any claims about such products are consistent with regulatory approvals, not misleading or false, and adequately substantiated by clinical data. Physicians may use pharmaceutical products off-label in their professional medical judgment, as the FDA does not restrict or regulate a physician's choice of diagnostic or treatment within the practice of medicine. However, the promotion of a product in a manner that is false, misleading, unsubstantiated, or for unapproved, or off-label, uses may result in enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or the FTC. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive regulatory approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. 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 sanctions and may result in false claims litigation under federal and state statutes, which can lead to consent decrees, civil monetary penalties, restitution, criminal fines and imprisonment, and exclusion

from participation in Medicare, Medicaid, and other federal and state healthcare programs. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Equivalent limitations and penalties are provided in the European Economic Area, or EEA, both at the supranational level and at the national level in the individual EEA countries.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products, if approved. Failure to comply with EU and EEA countries' laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of the marketing authorization, or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Moreover, the policies of the FDA and of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of [^{225}Ac]Ac-AKY-1189 or any of our other or future product candidates. As an example, the regulatory landscape related to clinical trials in the EEA recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each EEA country, leading to a single decision for each EEA country. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment by all EEA countries concerned, and a separate assessment by each EEA country with respect to specific requirements related to its own territory, including ethics rules. Each EEA country's decision is communicated to the sponsor via the centralized EU portal. Once the clinical trial approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials in relation to which application for approval was made on the basis of the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors could choose to submit a clinical trial application under either the Clinical Trials Directive or the CTR until January 31, 2023. Where these trials were authorized on the basis of the Clinical Trials Directive, they will be governed by the Clinical Trials Directive until January 31, 2025. Commencing on February 1, 2025, all ongoing trials are subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the clinical trial has already transitioned to the CTR framework. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our developments plans.

We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

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, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, similar foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval and licensure procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining similar foreign regulatory approvals and compliance with similar foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Disruptions at the FDA and other government agencies and foreign regulatory authorities, including those caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified drugs from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA or comparable foreign regulatory authorities to review and approve new drugs can be affected by a variety of factors, including government budget reductions in force, and funding levels, statutory, regulatory, and policy changes, the FDA's or comparable foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, pandemics and other public health crises, and other events that may otherwise affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Recent disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary regulatory authorities, which would adversely affect our business.

For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. In addition, the current U.S. presidential administration has issued certain policies and executive orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. If any future prolonged government shutdown occurs, or if renewed global health concerns, funding shortages or staffing limitations 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, financial condition, results of operations and prospects.

We are currently, and may in the future, conduct clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more additional clinical trials outside the United States, including in the EU, South Africa, Australia and/or Asia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for regulatory approval in the United States, the FDA will generally not approve the application based on foreign data alone unless: (i) the data is applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations.

Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in product candidates that we may develop not receiving approval for commercialization in such jurisdiction.

Our business operations and current and future relationships with healthcare professionals, principal investigators, consultants, vendors, customers, and third-party payors in the United States and elsewhere are subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings.

Healthcare providers, healthcare facilities and institutions, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our future arrangements with healthcare professionals, healthcare facilities and institutions, principal investigators, consultants, customers, and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, or the FCA, which may constrain

the business or financial arrangements and relationships through which we research, sell, market, and distribute any product candidates for which we obtain regulatory approval. In addition, we may be subject to physician payment transparency laws and regulation by the federal government and by the states and foreign jurisdictions in which we conduct our business. The applicable federal, state, and foreign healthcare laws and regulations that affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. 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 U.S. federal civil and criminal false claims laws, including without limitation, the civil FCA, which can be enforced by private citizens on behalf of the U.S. federal government through civil whistleblower or qui tam actions, and the federal civil monetary penalties law which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval 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 U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by, among other things, engaging in impermissible marketing practices, such as the off-label promotion of a drug for an indication for which it has not received FDA approval. Further, pharmaceutical manufacturers can be held liable under the civil FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, 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 civil FCA;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, 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 healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose obligations on certain healthcare providers, health plans and healthcare clearinghouses, known as covered entities, as well as their business associates and their subcontractors that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information. HITECH increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, and often are not preempted by HIPAA;
- the U.S. Federal Food, Drug, and Cosmetic Act, or the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices;
- the federal and state laws that require pharmaceutical manufacturers to report certain calculated drug prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the U.S. Physician Payments Sunshine Act and its implementing regulations, which requires, among other things, certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to certain payments and other transfers of value physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members;

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and
- similar healthcare laws and regulations in foreign jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Outside the United States, interactions between pharmaceutical companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is not always possible to identify and deter employee misconduct or business non-compliance, and the precautions we take to detect and prevent inappropriate conduct 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. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of [^{225}Ac]Ac-AKY-1189 of any of our other current or future product candidates, if approved. Compensation under some of these arrangements includes the provision of stock or stock options in addition to cash consideration. Because of the complex and far-reaching nature of these laws, it is possible that if our products are commercialized, governmental authorities could 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 of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be in violation of applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Healthcare policy changes may have a material adverse effect on our business, financial condition, results of operations and prospects.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, enacted in March 2010, made several substantial changes in the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. Some ways in which the ACA may significantly impact our business include provisions regarding coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, and initiatives to promote quality indicators in payment methodologies.

There have been legal and political challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021, through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and current or evolving federal policies regarding healthcare reform measures will impact the ACA or our business.

Since the ACA's passage, legislative changes to the ACA have been proposed and adopted. On July 4, 2025, the annual reconciliation bill, the "One Big Beautiful Bill Act," or OBBBA, was signed into law which is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. OBBBA also narrows access to ACA marketplace exchange enrollment and declines to extend the ACA's enhanced advanced premium tax credits, set to expire in 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. Additionally, under the sequestration required by the Budget Control Act of 2011, beginning April 1, 2013, Medicare payments to providers were reduced, which will remain in effect through 2032 unless additional Congressional action is taken. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on the Medicaid drug rebate effective January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed drugs, 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 drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively in fiscal year 2023, although the drug price negotiation program is currently subject to legal challenges. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In addition, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological drug pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Our ability to develop and market new drug products may be impacted if litigation challenging the FDA's approval of another company's drug continues. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product, which was originally approved in 2000, and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed and remanded that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. Depending on the outcome of this litigation, if it continues, our ability to develop [^{225}Ac]Ac-AKY-1189 or future product candidates we may develop may be at risk and could be delayed, undermined or subject to protracted litigation. Finally, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as FDA acted within its statutory authority under the Administrative Procedure Act, or the APA. Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held

that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and the CMS that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations. Furthermore, recent changes to the leadership of federal agencies like HHS, CMS and FDA can lead to new policies and regulations that can have a material impact on our industry and business operations.

Many EEA countries periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EEA countries will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EEA countries, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EEA countries, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EEA countries. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EEA countries.

In December 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EEA countries in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EEA level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EEA countries to use common HTA tools, methodologies, and procedures across the EEA, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EEA countries will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EEA countries for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EEA could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the EEA may continue to propose and implement cost-containing measures to keep healthcare costs down; particularly due to the financial strain that the COVID-19 pandemic placed on national healthcare systems of the EEA countries. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EEA and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, supranational or national level, or how any future legislation or regulation may affect us, any of which may have a materially adverse effect on our business, financial condition, results of operations and prospects.

Even if we are able to commercialize a product candidate, coverage and adequate reimbursement may not be available or such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing, and reimbursement for product products vary widely from country to country. Some countries require approval of the sale price of a drug product before it can be marketed or may require us or our collaborators to conduct clinical trials that compare the cost-effectiveness of our product candidates to other therapies to obtain reimbursement or pricing approval. In many countries, the pricing review period begins after regulatory approval is granted. In some foreign markets, prescription drug product pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to

recoup our investment in one or more product candidates, even if [^{225}Ac]Ac-AKY-1189 or any of our future product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors, such as government authorities, private health insurers, and other organizations. Even if we succeed in bringing one or more products to market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of coverage and reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for drug products. Moreover, no uniform policy requirement for coverage and reimbursement for drugs exists among third-party payors in the United States, which may result in significant variations in coverage and reimbursement from payor to payor. Even if favorable coverage and reimbursement status is attained for one or more drug products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. If the price we are able to charge for any products we develop, or the coverage and reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be affected adversely.

The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for [^{225}Ac]Ac-AKY-1189 or any of our other current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Our inability to promptly obtain and maintain coverage and adequate reimbursement from both third-party payors for the product candidates that we may develop and for which we obtain regulatory approval could adversely affect our business, financial condition, results of operations, and prospects.

We and our collaborators and our third-party service providers are subject to a variety of stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and industry standards related to data privacy and cybersecurity, which could increase compliance costs, and our actual or perceived failure to comply therewith could subject us to regulatory investigations or actions, litigation, fines or penalties, disruptions of our business operation, reputational harm, loss of revenue or profits, and other adverse business consequences.

We process a large quantity of sensitive information, including proprietary and confidential business information and other personal information, and we and our collaborators and third-party service providers are subject to various federal, state, local and foreign data privacy and cybersecurity laws, rules and regulations relating to the privacy, security and processing of personal information.

The global data privacy and cybersecurity landscape is rapidly evolving, and we and our collaborators and third-party service providers may be affected by or subject to new, amended, or existing laws, rules and regulations, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws, rules and regulations may be subject to differing interpretations, which adds to the complexity of processing personal information. Guidance on implementation and compliance practices are often updated or otherwise revised. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer, use, share or otherwise process personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. If we fail or are perceived to have failed to comply with these laws, rules and regulations, we may be subject to litigation, regulatory investigations, enforcement notices, enforcement actions, fines, imprisonment of company officials and public censure, claims for damages by affected individuals, and criminal or civil penalties, as well as negative publicity, reputational harm, loss of goodwill and a potential loss of business, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In the United States, numerous federal, state and local laws, rules and regulations, including state data breach notification laws and federal and state data privacy laws, rules and regulations that govern the collection, use, disclosure, protection, transfer and other processing of health information and other personal information apply to our operations and the operations of our collaborators and third-party service providers. Each of these laws, rules and regulations is subject to varying interpretations and constantly evolving.

For example, HIPAA, as amended by HITECH, and regulations promulgated thereunder impose certain obligations with respect to safeguarding the privacy, security, transmission and other processing of individually identifiable health information on "covered entities," and their respective "business associates," as well as their covered subcontractors, that perform services for them. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. For example, under HIPAA, we could potentially face substantial criminal or civil penalties if we knowingly receive protected health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of such protected health information, or otherwise violate applicable HIPAA requirements related to the protection of such information. Moreover, determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations with third parties can be complex and may be subject to changing interpretation. If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. The HHS has the discretion to impose penalties without attempting to first resolve violations. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources.

Even when HIPAA does not apply, failing to take appropriate steps to keep consumers' personal information secure may constitute a violation of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. In connection with our clinical trials, we may maintain sensitive identifiable personal information, including health information, that we receive throughout the clinical trial process, during our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may become subject to further obligations under HIPAA.

In addition, our collection of personal information generally may subject us and our collaborators and third-party service providers to state data privacy laws governing the processing of personal information, including requiring us to reasonably protect certain types of personal information we hold or to otherwise comply with certain specified cybersecurity requirements with respect to personal information and requiring notification of affected individuals and state regulators in the event of a breach of such personal information in certain instances. For example, these state laws include the California Consumer Privacy Act, as amended by the California Privacy Rights Act, or collectively the CCPA, and applies to personal information of consumers, business representatives and employees that are California residents and requires covered businesses to make disclosures to consumers about their data collection, use and sharing practices, allows consumers to opt out of certain data sharing with third parties and provides a cause of action for data breaches. The CCPA provides for significant civil penalties of up to $7,500 per violation as well as a private right of action for certain data breaches and statutory damages. Although there are limited exemptions for clinical trial data and some other health data under the CCPA, the CCPA and other similar laws may impact our business activities and increase our compliance costs. Additionally, the California Privacy Rights Act, effective in most material respects as of January 1, 2023, expanded data privacy and cybersecurity compliance requirements and consumers' rights under the CCPA including by, among other things, giving California residents the ability to correct their personal information and limit use of certain sensitive personal information, establishing restrictions on the retention of personal information, expanding the types of data breaches subject to the CCPA's private right of action, and establishing a new California Privacy Protection Agency to implement and enforce the law. Other states, including but not limited to Virginia, Colorado, Utah, and Connecticut, have also passed comprehensive privacy laws, and similar laws are being considered in several other states (including Washington, which enacted the My Health, My Data Act in 2023), as well as at the federal and local levels. While many of these states, like California, also exempt some data processed in the context of clinical trials, these laws could have potentially conflicting requirements that further complicate compliance efforts, and increase legal risk and compliance costs for us, and the third parties upon whom we rely.

In addition, all 50 U.S. states and the District of Columbia have enacted breach notification laws that may require us to notify patients, employees or regulators in the event of unauthorized access to or disclosure of personal or confidential information experienced by us or our collaborators or third-party service providers. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify patients or other counterparties of a security breach. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards.

Any clinical trial programs and research collaborations that we engage in outside the United States may implicate international data protection laws, including, in Europe, the General Data Protection Regulation, or GDPR, and the United Kingdom's GDPR, combining the GDPR and the UK's Data Protection Act of 2018, or the UK GDPR. The GDPR and UK GDPR govern the collection, use, disclosure, transfer or other processing of personal data of individuals within the EEA and UK and impose stringent operational requirements for data processors and controllers of personal data. For example, the GDPR and UK GDPR impose onerous

accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. The GDPR and UK GDPR also impose certain other onerous obligations, including obligations for controllers and processors to appoint data protection officers in certain circumstances, increased transparency obligations to data subjects for controllers, obligations to honor increased rights for data subjects, and obligations to implement certain technical and organizational safeguards to protect the security and confidentiality of personal data. The GDPR and UK GDPR also provide that EEA member states and the UK make their own further laws, rules and regulations to introduce specific requirements related to the processing of "special categories of personal data," including personal data related to health, biometric data used for unique identification purposes and genetic information, as well as personal data related to criminal offences or convictions. This fact may lead to greater divergence on the law that applies to the processing of such data types across the EEA and the UK, compliance with which, as and where applicable, may increase our costs and could increase our overall compliance risk. Such member state specific regulations could limit our ability to collect, use and share data in the context of any future EEA or UK establishments (regardless of where any processing in question occurs). Among other things, the GDPR and UK GDPR require detailed notices for clinical trial subjects and investigators as well as the security of personal information, and notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects. In addition, the GDPR and UK GDPR materially expanded the definition of what constitutes personal data (including, for example, by expressly clarifying that the GDPR applies to "pseudonymized" and key-coded data).

Since January 1, 2021, when the transitional period following the exit of the UK from the EU, or Brexit, expired, companies required to comply with the GDPR are also required to comply with the UK GDPR, which exposes these companies to two parallel regimes, each of which authorizes similar fines and may subject them to increased compliance risk based on differing, and potentially inconsistent or conflicting, interpretation and enforcement by regulators and authorities (particularly, if the laws are amended in the future in divergent ways). While the GDPR and the UK GDPR remain substantially similar for the time being, the government of the UK has adopted reforms to its data privacy and cybersecurity legal framework in its Data Use and Access Act 2025, which became law on June 19, 2025 (phasing in between June 2025 and June 2026) and will introduce significant changes from the GDPR. This may lead to additional compliance costs and could increase overall risk exposure as businesses may no longer be able to take a unified approach across the EEA and the UK, and such businesses may need to amend their processes and procedures to align with the new framework. Implementing mechanisms to endeavor to ensure compliance with the GDPR and the UK GDPR may be onerous and expose businesses to divergent parallel regimes that may be subject to potentially different interpretations and enforcement actions for certain violations and related uncertainty. With respect to transfers of personal data from the EEA, on June 28, 2021, the European Commission issued an adequacy decision in respect of the UK's data protection framework, enabling data transfers from EU member states to the UK to continue without requiring organizations to put in place contractual or other measures in order to lawfully transfer personal data between the territories. However, the UK adequacy decision will automatically expire in December 2031 unless the European Commission re-assesses and renews or extends that decision and remains under review (and may be modified or revoked) by the Commission during this period. In addition, transfers of personal data from the UK to other countries, including the EEA, are subject to specific transfer rules under the UK regime.

The GDPR and UK GDPR impose substantial fines for breaches and violations (up to the greater of €20 million or 4% of consolidated annual worldwide gross revenue under the GDPR or GBP 17.5 million under the UK GDPR). In addition to administrative fines, a wide variety of other potential enforcement powers are available to competent supervisory authorities in respect of potential and suspected violations of the GDPR or the UK GDPR, including extensive audit and inspection rights, and powers to order temporary or permanent bans on all or some processing of personal data carried out by non-compliant actors The GDPR and UK GDPR also confer a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR or the UK GDPR. Further, the exit of the UK from the EU and ongoing developments in the UK have created uncertainty regarding data protection regulation in the UK.

Certain legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States, which will affect us if we begin to transfer personal data from the EEA to other jurisdictions. In July 2023, the European Commission adopted an adequacy decision in relation to the new EU-U.S. Data Privacy Framework, or DPF, rendering the DPF effective as a GDPR transfer mechanism for personal data transferred from the EEA to the United States by United States entities self-certified under the DPF. However, the DPF adequacy decisions do not foreclose, and are likely to face, future legal challenges and the ongoing legal uncertainty with respect to international data transfers may increase our costs and our ability to efficiently process personal data from the EEA. Other data transfer mechanisms such as the Standard Contractual Clauses approved by the European Commission have faced challenges in European courts, may require additional risk analysis and supplemental measures to be used, and may be challenged, suspended or invalidated. Loss of our ability to lawfully transfer personal data out of the EEA and UK to the United States or any other jurisdictions may require us to increase our data processing capabilities in the EEA and UK at significant expense. If we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we perform our operations or provide our services, the geographical location or segregation of our relevant systems and operations, and adversely affect our financial results. These international laws, rules and regulations may apply not only to us, but also to our collaborators, vendors or other third-party service providers that store

or otherwise process personal data on our behalf, such as information technology vendors, and any of the foregoing limitations could impact our ability to work with such collaborators or third-party service providers in certain jurisdictions.

We are bound by contractual obligations related to data privacy and cybersecurity, and our efforts to comply with such obligations may not be successful. For example, certain data privacy laws, such as the EU GDPR, the UK GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and cybersecurity. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and cybersecurity are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflicting among jurisdictions. We are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable data privacy and cybersecurity laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations or policies, even if we are not found liable, could be expensive and time-consuming to defend, and could result in adverse publicity that could harm our business. Moreover, even if we take all necessary action to comply with legal and regulatory requirements, we could be subject to data breaches or other unauthorized access of personal information or other sensitive or confidential information, which could subject us to fines and penalties, as well as litigation and reputational damage and other adverse consequences.

If we or our collaborators or our third-party service providers fail to keep apprised of and comply with applicable international, federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to seek to commercialize our product candidates. Any threatened or actual governmental enforcement action or litigation where private rights of action are available could also generate adverse publicity, damage our reputation, result in liabilities, fines, and loss of business, and require that we devote substantial resources that could otherwise be used in other aspects of our business.

With laws, rules, regulations, and other obligations relating to data privacy and cybersecurity imposing new and relatively burdensome obligations, and with the substantial uncertainty over the interpretation and application of these and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices and may incur significant costs and expenses in an effort to do so. We are currently in the process of developing and updating our policies and procedures in accordance with requirements under applicable data privacy and cybersecurity laws, rules and regulations and have not completed formal assessments of whether we are in compliance with all applicable data privacy and cybersecurity laws, rules and regulations. Additionally, if third parties with which we work, such as our collaborators, vendors or other third-party service providers, violate applicable laws, rules or regulations or our policies, such violations may also put our or our clinical trial and employee data, including personal or other sensitive or confidential information, at risk, and our business, financial condition, results of operations, and prospects may be adversely affected.

We are subject to certain U.S. and foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector.

We expect to have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations, and we expect our international activities to increase in time. We may engage third parties to conduct clinical trials, obtain necessary permits, licenses, patent registrations and other regulatory approvals or sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of

export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

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 have a material adverse effect on 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, including radioactive materials and gas. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive 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 our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Our use of facilities that use and produce radioactive materials subjects us to compliance with decommissioning and decontamination, or D&D, requirements when we close those facilities, exposing us to potentially significant costs. Our product candidates are manufactured using radioactive components, such as the radioisotope ^{225}Ac. When one of such facilities reaches the end of its useful life or if we need to abandon such facility for any other reason, we are obligated under the laws and regulatory rules of the various jurisdictions in which we operate to decommission and decontaminate such facility. We have no experience with D&D, and the costs of such D&D may be substantial. Estimating the amount and timing of such future D&D costs includes, among other factors, country-specific requirements and projections as to when a facility will retire or the useful life of a facility. If we do not conduct D&D properly at any of our sites, we may suffer significant additional costs to remediate any D&D deficiencies, fines, regulatory or criminal charges or other sanction or legal action, any of which could have a material adverse effect upon our business, financial condition and results of operations. Although we have estimated our future D&D costs and recorded a liability for such costs, there can be no assurances that we will not incur material D&D costs beyond such estimates or our provisions.

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, and 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 our storage or disposal of biological, hazardous, or radioactive materials. In addition, we may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development, and production efforts, which could harm our business, financial condition, results of operations or prospects.

Risks related to manufacturing

We intend to build and operate our own manufacturing facility for preclinical and clinical supply needs, which will require significant resources, and we may fail to successfully establish and operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.

We are currently establishing and building a manufacturing facility, in addition to our reliance on CDMOs for the manufacture of our product candidates for preclinical and clinical needs. We expect that construction of our own manufacturing facility will provide us with enhanced control of material supply for preclinical studies and clinical trials, enable the more rapid implementation of process changes, and allow for better long-term cost efficiencies. However, we have no experience as a company in construction of a manufacturing facility and may never be successful in building our own manufacturing facility or capability. As a result, we will also need to hire additional personnel to manage our operations and facilities and develop the necessary infrastructure to continue the research and development and manufacture of our product candidates. We, as a company, have no experience in setting up, building, or eventually managing a manufacturing facility. If we fail to complete the planned construction and buildout in an efficient manner, or fail to recruit the required personnel and generally manage our growth effectively, the development and production of our product candidates could be curtailed or delayed. Even if we are successful, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business. Furthermore, if we are successful in building our own manufacturing facility, we will continue to be reliant on our CDMOs for clinical and commercial supply, if our product are approved, and their continued compliance with relevant regulations.

In addition, the FDA, the EMA, and other foreign regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA, or other foreign regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results

of operations, and prospects. Problems in our manufacturing process could restrict our ability to meet clinical and market demand for our products.

Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

Our product candidates are biologics and the manufacture of our product candidates is complex. Even after our planned manufacturing facility is operating, we will continue to rely on third parties to manufacture our product candidates. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product supplies or product candidates, or fail to do so at acceptable quality levels or prices.

Our product candidates are biologics and the process of manufacturing them is complex, highly regulated and subject to multiple risks. As a result of these complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process for biologics is less reliable and is more difficult to reproduce. In addition, manufacturing our product candidates will require many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We have experienced manufacturing deviations and similar issues in the past, and may experience similar issues in the future. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Any such issues could cause delays in our development plans. Further, as product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials.

Even if we are able to complete our manufacturing facility, we will continue to rely on U.S.-based third-party manufacturers or third-party collaborators for the manufacture of our product candidates and for commercial supply of any of our product candidates for which we or any of our potential future collaborators obtain marketing approval. We may be unable to maintain agreements with our existing third-party manufacturers, or to establish additional 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:

- the number of potential manufacturers is limited and any new manufacturers are subject to the FDA's review and approval of a supplemental BLA. This approval would require new testing and may require pre-approval inspections of the new manufacturer by the FDA. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products;
- our current third-party manufacturers are located in United States and we may encounter issues with exporting our product candidates into foreign jurisdictions;
- our third-party manufacturers might be unable to timely manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- our third-party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our third-party manufacturers may not perform as agreed, according to our schedule or specifications, or at all, may not devote sufficient resources to our product candidates, may give greater priority to the supply of other products over our product candidates, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products;
- our third-party manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with GMPs and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these and/or any other applicable regulations and standards;

- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products;
- our third-party manufacturers could breach, terminate or not renew their agreement with us at a time that is costly or inconvenient for us;
- clinical and, if approved, commercial supplies for the raw materials and components used to manufacture and process our product candidates, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active product or placebo not being properly identified;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of product supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- our third-party manufacturers may have unacceptable or inconsistent product quality success rates and yields.

Our third-party manufacturers and clinical reagent suppliers may be subject to regulatory requirements or sanctions, as well as damage or interruption from, among other things, fire, natural or man-made disaster, power loss, telecommunications failure, unauthorized entry, computer viruses, denial-of-service attacks, acts of terrorism, human error, vandalism or sabotage, financial insolvency, bankruptcy and similar events.

We currently engage WuXi Biologics (Hong Kong) Limited, or WuXi, with respect to the manufacture of miniprotein variants and recombinant production and pharmacokinetic studies unrelated to [^{225}Ac]Ac-AKY-1189 and [^{225}Ac]Ac-AKY-2519. Certain Chinese biotechnology companies and CMOs, including WuXi, may in the future become subject to trade restrictions, sanctions, and other regulatory requirements 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. The recently proposed BIOSECURE Act would have banned U.S. government contracts, grants, and loans from being used towards biotechnology equipment and services produced or provided by certain named Chinese biotechnology companies, including WuXi, and would authorize the U.S. government to name additional Chinese biotechnology companies of concern. The legislation did not pass the U.S. Congress in 2024; however, on December 18, 2025, the BIOSECURE Act was passed as part of the final Fiscal Year 2026 National Defense Authorization Act. Although the newly passed act does not explicitly name WuXi, or any other companies in the statute, the BIOSECURE Act bans federal procurement or funding associated with "biotechnology companies of concern" and restricting use of their equipment and services in federal contracts, grants, and loans. The implementation of the act will be phased in over a period of years, and could severely restrict the ability of companies to work with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government.

The new administration has substantially altered prior U.S. government international trade policy and has commenced activities to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements and treaties with foreign countries. In addition, the new administration has initiated or is considering imposing tariffs on certain foreign goods. Related to this action, certain foreign governments, including China, have instituted or are considering imposing tariffs on certain U.S. goods. It remains unclear what the new policies by the U.S government or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers, increase the cost of materials purchased to manufacture our products, impact our ability to sell our products outside the U.S. or to sell our products outside the U.S. at competitive prices and/or to affect the U.S. or global economy or certain sectors thereof and, thus, could adversely impact our business.

If the third parties we engage to supply materials or manufacture product candidates or products for preclinical testing or clinical or commercial supply should cease to do so for any reason, we would likely experience delays in advancing these preclinical tests and clinical trials and/or interruptions in commercial supply while we identify and qualify replacement suppliers or manufacturers, and we may be unable to obtain replacement supplies on terms that are favorable to us, or at all. If we are not able to obtain adequate supplies of our product candidates or products or the substances used to manufacture them, it could materially and adversely impact our business, prospects, operating results or financial condition.

Each of these risks could delay or prevent the completion of our ongoing and future clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. Any shortages in the supply of such raw materials used in the manufacture of our product candidates could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we may rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our company until deficiencies are remedied.

The facilities used by our contract manufacturers to manufacture our product candidates may be subject to inspections that will be conducted after we submit our BLA to the FDA. We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations. Any product candidates that we may develop may compete with product candidates of other companies 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 failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including 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 and harm our business and results of operations.

Our contract manufacturers' failure to achieve and maintain high manufacturing standards, in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury or death, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel.

We may be unable to obtain a sufficient supply of ^{225}Ac or other radioisotopes to support clinical development or manufacturing at commercial scale.

^{225}Ac is a key component of [^{225}Ac]Ac-AKY-1189 and [^{225}Ac]Ac-AKY-2519 and, as a radiopharmaceutical company, we expect our future product candidates to include ^{225}Ac or other isotopes. Although we believe our present suppliers have adequate quantities of ^{225}Ac and labeling isotopes available to meet our current needs, we may encounter supply shortages which could affect our business operations and results of operations. There can be no assurance that our suppliers will renew the contracts on acceptable terms, or at all. Further, long-term suppliers are not yet producing beyond minimal research quantities and there is no guarantee they will come online in the time frame we expect. Even when a contract exists, we have very limited recourse under our current supply contracts if a supplier is unable to meet its obligations. Suppliers may be unable to meet their obligations for a number of reasons, for example, the U.S. Department of Energy has reserved its ability to cancel private orders when the supply is instead needed for national defense, environmental safety or there is a lack of capacity, and the likelihood of any such cancellation may be increased for a number of reasons. There are not many alternatives to our current suppliers, and finding any replacement suppliers would divert management resources. Failure to acquire enough medical-grade ^{225}Ac would make it impossible to effectively complete clinical trials, especially as we scale up for later-stage clinical trials, and to commercialize any ^{225}Ac-based product candidates that we may develop and would materially harm our business.

To date, we have obtained the ^{225}Ac for our ongoing Phase 1b clinical trial of [^{225}Ac]Ac-AKY-1189 from several United States and foreign-based suppliers pursuant to long-term supply agreements. In the event we are unable to source ^{225}Ac from our current suppliers, we may seek to source ^{225}Ac from other sources, including those located in Russia. This could expose us to additional environmental and geopolitical risks, including restrictions on trade of certain items between the United States and Russia, and other unforeseen geopolitical factors that limit our ability to access our supply of raw material. For example, any Russian supplier may become designated on export-or sanctions-related restricted party lists maintained by the U.S. government. Our ability to conduct clinical trials to advance our product candidates is dependent on our ability to obtain these radioisotopes and other isotopes we may choose to utilize in the future. We expect to remain dependent on third-party manufacturers and suppliers for our isotopes. These parties may not perform their contracted services or may breach or terminate their agreements with us. Our suppliers are subject to regulations and standards that are overseen by regulatory and government agencies and we have no control over our suppliers' compliance to these standards. Failure to comply with regulations and standards may result in their inability to supply isotope could result in delays in our clinical trials, which could have a negative impact on our business. Our inability to build out and establish our own manufacturing facilities would require us to continue to rely on third-party suppliers, as we currently do.

Changes in the methods of manufacturing or formulation of our product candidates may result in additional costs or delay.

As our product candidates progress through clinical trials to regulatory approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, may be altered along the way in an effort to optimize safety, efficacy, yield, and manufacturing batch size, minimize costs, and achieve consistent quality and results. There can be no assurance that any future manufacturing or formulation changes will achieve their intended objectives. These changes and any future changes we may make to our product candidates may also cause such candidates to perform differently and affect the results of future clinical trials conducted with the altered materials. Such changes or related unfavorable clinical trial results could delay initiation or completion of additional clinical trials, require the conduct of bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay or prevent potential regulatory approval, and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

Risks related to related to our dependence on third parties

We rely on third parties to conduct the Phase 1b clinical trial of [^{225}Ac]Ac-AKY-1189 and plan to rely on third parties to conduct our future clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We depend and will continue to depend on independent investigators and collaborators, such as medical institutions, CROs, CMOs, CDMOs, and strategic partners to conduct our preclinical studies and clinical trials, including with respect to our ongoing Phase 1b clinical trial for [^{225}Ac]Ac-AKY-1189. We expect to have to negotiate budgets and contracts with CROs, CDMOs, CMOs and trial sites which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these clinical trials and the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or similar foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMP regulations, and will require a large number of patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing, clinical and preclinical product candidates. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

As a result of the bankruptcy of one our CROs in 2025, we migrated to another provider. Switching or adding third parties to conduct our clinical trials or preclinical studies involves substantial cost and requires extensive management time and focus and may ultimately be unsuccessful. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We have in place certain collaboration and licensing arrangements, and may form or seek collaborations, strategic alliances or licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We have in place certain collaboration and licensing arrangements, and in the future, we may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. For example, in May 2024, we entered into a research, collaboration and license agreement with Eli Lilly to discover and generate novel tumor-targeting radiopharmaceuticals. For more information on this and other arrangements, see "Business—License and collaboration agreements." Any of these current or future relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business. We cannot guarantee you that our current or future partners will not terminate their collaboration, or seek to change terms of the collaboration, with us.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a 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. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or applicable foreign regulatory authorities, 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 and the existence of uncertainty with respect to its 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, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates

as having the requisite potential to demonstrate safety, potency and purity and obtain marketing approval. In certain cases, when we collaborate with a third party for the development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain, enforce, protect or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, we may not be able to realize the benefit of our current or future collaborations, joint ventures, strategic partnerships or licensing arrangements if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. If our existing or future collaborations are terminated or suspended, we may not be able to identify other suitable collaborators or reach agreement with other suitable collaborators on a timely basis, on acceptable terms or at all. If we are unable to continue our current or future collaborations or are unable to identify or reach agreement with other suitable collaborators, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, increase our expenditures or needs for additional capital to pursue further development or commercialization of the applicable product candidates or undertake development or commercialization 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 and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operation. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications. Any of the foregoing could have a material adverse effect on our business, prospects, financial condition and results of operations.

If we or third parties, such as CROs, CDMOs, CMOs, use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities may involve the controlled use of potentially hazardous substances, including chemicals and biological and radioactive materials, by us or third parties, such as CROs, CDMOs and CMOs. The use of ^{225}Ac-labeled miniproteins treatments involves the inherent risk of exposure from gamma ray emissions, which can alter or harm healthy cells in the body. We and such third parties are subject to federal, state, provincial and local laws and regulations in the United States and other foreign jurisdictions governing the use, manufacture, storage, handling, and disposal of medical and hazardous materials. Although we believe that our and such third-parties' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state, provincial or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition, or results of operations. We currently maintain insurance coverage for injuries resulting from the hazardous materials we use; however, future claims may exceed the amount of our coverage. Also, we do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with such federal, state, provincial, local and foreign environmental regulations are not significant, and consist primarily of waste disposal expenses. However, they could become expensive, and current or future environmental laws or regulations may impair our research, development, production and commercialization efforts.

Our employees, independent contractors, principal investigators, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, directors or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, securities, and patient privacy and other privacy laws and regulations. Misconduct by employees could include failures to comply with FDA regulations and equivalent foreign regulations, provide accurate information to the FDA or competent foreign regulatory authorities, comply with manufacturing standards we may establish, comply with federal and state or national healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. Sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, labeling, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Employee misconduct could also involve the improper use of information obtained during clinical trials, which could result in regulatory sanctions and serious harm to our reputation. In addition, our reputation may be harmed if any of our employees, directors, independent contractors, principal investigators or consultants are found to have been involved in similar misconduct outside of their services to our Company. 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 comply 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, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or equivalent foreign programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with the law, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business or pursue our strategy.

Risks related to intellectual property

We do not own or expect to own any issued patents relating to the radioactive payload, ^{225}Ac, used in our product candidates, including [^{225}Ac]Ac-AKY-1189 and [^{225}Ac]Ac-AKY-2519.

We do not own or license, and do not expect to own or license, any patents or patent applications that cover the radioactive payload, ^{225}Ac, in our product candidates. Composition-of-matter patent claims in pharmaceutical products are generally considered to be the favored form of intellectual property protection for products because such patents may provide protection without regard to any particular method of use or manufacture or formulation of the composition of matter used. For example, formulation and method-of-use patent claims do not prevent a competitor or other third party from marketing an identical radioactive payload for an indication that is outside the scope of the method claims or from developing a different formulation that is outside the scope of the formulation claims.

With respect to AKY-1189, as of March 1, 2026, we own one patent family, including one pending Patent Cooperation Treaty, or PCT, Application, one issued U.S. patent, one pending U.S. non-provisional application, and two pending ex-US non-provisional patent applications directed to composition of matter of AKY-1189 and methods of use. With respect to AKY-2519, as of March 1, 2026, we own one patent family, including one pending PCT Application, one pending U.S. non-provisional application, and two pending ex-U.S. non-provisional patent applications directed to composition of matter of AKY-2519 and methods of use. We cannot predict whether our patent applications will result in the issuance of any patents that provide us with any competitive advantage. We have one issued patent relating to our product candidates, in particular, AKY-1189, and do not currently have any issued patents relating to AKY-2519. It is also possible that others will design around any future patents we may obtain. Further, any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies. In addition, any future patents we obtain may be narrowed or found to be invalid or unenforceable.

Any patent that issues from national stage entries of the aforementioned pending PCT application or either of the two foreign patent applications and any future non-provisional patent applications that we may file claiming priority to these patent applications are expected to expire in 2044, excluding any patent term adjustments and extensions that may be available. We cannot be certain that we will obtain issued patents based on our current and future patent applications, and if obtained, whether they can provide meaningful protection for our product candidates or any future product candidates or whether they will remain in force through their expected expiration date. If we do not obtain and maintain meaningful patent coverage for our product candidates, their respective components, formulations, combination therapies, methods of manufacture, and methods of treatment, competitors may be able to erode or negate any competitive advantage we may have, which would likely harm our business and ability to achieve profitability. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our success depends on our ability to obtain, maintain, enforce, defend and protect our intellectual property and our proprietary technologies, and conduct our business without infringing, misappropriating or otherwise violating intellectual property or proprietary rights of others.

Our commercial success depends, in part, on our ability to obtain, maintain, enforce, defend and protect our intellectual property rights, including patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon, misappropriating or otherwise violating the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. We may also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending patent applications or other intellectual property or proprietary rights from third parties. If we or our current or future licensors are unable to obtain or maintain patent protection with respect to our product candidates and other proprietary technologies we may develop, it could have a material adverse effect on our business, financial condition, results of operations and prospects.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. Our owned and in-licensed patent portfolio is at an early stage. We currently own one issued patent relating to one of our product candidates, [^{225}Ac]Ac-AKY-1189. We do not currently own or in-license any other issued patents relating to any product candidates, including [^{225}Ac]Ac-AKY-1189, or otherwise. There can be no assurance that our patent applications or the patent applications of our current or future licensors will result in patents being issued or that issued patents will afford sufficient protection against competitors or other third parties with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts in the United States and abroad. The degree of future protection for our and our licensors' intellectual property or other proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property or other proprietary rights relating to our product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

As of June 1, 2023, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or UPC. This is a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation.

We cannot be certain that the claims in our U.S. pending patent applications, our pending international patent applications and any patent applications that we may file in the future in the United States or foreign territories, or those of our current or future licensors, will be considered patentable by the United States Patent and Trademark Office, or USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our future issued patents will not be found invalid or unenforceable if challenged. Even if they are unchallenged, our owned and licensed patent applications, and any patents we obtain, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies in a non-infringing manner. If the patent protection provided by the patent applications we own or license and any patents we obtain is not sufficiently broad to

impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining, maintaining, enforcing, protecting and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the non-compliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors or other third parties, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents or other intellectual property rights that will limit, interfere with or eliminate our ability to make, use and sell our product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is expensive, time-consuming and complex, and we and any current or future licensors may not be able to file, prosecute, maintain, enforce, protect, defend or license all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we or any current or future licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain or maintain valid and enforceable patent protection. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or until issuance, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable.

In addition, 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 intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our current or future licensors may not result in patents being issued which protect our product candidates and other proprietary technologies we may develop, or which effectively prevent others from commercializing competitive technologies and product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the corresponding patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license issue as patents in the future, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we in the future own, or in-license,

may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates or other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent issues, our competitors or other third parties may be able to circumvent our patents or the patents of our current or future licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents, if issued, or the patents of our current or future licensors may be challenged in the courts or patent offices in the United States and abroad. We or any of our licensors may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, or PGR, and inter partes review, or IPR, or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, our future patents or the patents of our current or future licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents, if issued, and patent applications or those of our current or future licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, 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 product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents, if issued, and patent applications or those of our current or future licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Moreover, some of our patent applications and future patents are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents and patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of such patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing, could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may not be able to obtain and protect our intellectual property rights throughout the world.

Patents are of national or regional effect. Filing, prosecuting, maintaining, enforcing, protecting and defending patent rights and other proprietary rights on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In some cases, we or our licensors may not be able to obtain patent protection for certain technology outside the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, even in jurisdictions where we or our licensors do pursue patent protection, or from selling or importing products made using our or our licensors' inventions in and into the United States or other jurisdictions. Competitors or other third parties may use our technologies in jurisdictions where we and our licensors have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our and our licensors' patent applications, if issued, or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceuticals and biotechnology products, which could make it difficult for us to stop the infringement of our patents, if issued, or marketing of competing products in violation of our intellectual property and proprietary rights. In addition, some jurisdictions, such as the Europe, Japan, and China, may have a higher standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Proceedings to enforce our or our licensors' intellectual property and proprietary rights in the United States and foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patent rights at risk of being invalidated or interpreted narrowly, could put our owned or in-licensed patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Various countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner in these countries may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we or any of our licensors are forced to grant a license to third parties with respect to any patent rights relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Geo-political actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our future issued patents or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of any future patents or patent applications in Russia, resulting in partial or complete loss of patent rights in Russia. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies and product candidates. While we will endeavor to try to protect our technologies and product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time consuming, expensive, and unpredictable. Any of the foregoing events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Obtaining, maintaining, enforcing, protecting and defending our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and 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 patent applications will be due to be paid to the USPTO and various foreign patent agencies at various stages over the lifetime of our owned or licensed patent rights. We have systems in place to remind us to pay these fees, and we rely on our outside counsel and its outside patent annuity service to pay these fees when due. In addition, the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. We seek to employ reputable law firms and other professionals to help us comply with these provisions. 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 a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction, including as a result of failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market. Our ability to comply with the various procedural, documentary, fee payment and other requirements imposed by regulations and governmental patent agencies could also be reduced or eliminated in the event of natural disasters, pandemics, or other catastrophic events. If such an event were to occur, including with respect to the patent rights covering our research programs and product candidates, as well as their respective methods of use, manufacture, and formulations thereof, it could have a material adverse effect on our business, financial condition, results of operations and prospects, as for example, competitors might be able to enter the market earlier than would otherwise have been the case.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive 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 or licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property and other proprietary rights, particularly patents. Obtaining, maintaining, enforcing, defending and protecting intellectual property and other proprietary rights, including patent rights in the biotechnology and pharmaceutical industries involve a high degree of technological and legal complexity. Therefore, obtaining, maintaining, enforcing, defending and protecting biotechnology and pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our future patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

The patent positions of companies engaged in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain patents or to enforce the patents we might obtain or license in the future. Any of the foregoing could have a material adverse effect on our owned and in-licensed patent portfolio and our ability to protect and enforce our intellectual property in the future, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our current or future licensors and the enforcement or defense of our future issued patents or those of our current or future licensors.

On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes several significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period after filing or until issuance, we may not be certain that we or our current or future licensors are the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also includes several significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of

our current or future licensors and the enforcement or defense of our future issued patents or those of our current or future licensors, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration, and specifics of FDA regulatory approval of our product candidates, one or more patents issued from U.S. patent applications that we file or those of our current or future licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during the FDA regulatory review process based on the first regulatory approval for a particular drug or biologic. A maximum of one patent may be extended per FDA-approved drug as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates.

However, we may not be granted an extension for which we apply in the United States or any other jurisdiction 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 or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party.

If we are unable to obtain patent term extension or restoration, or the foreign equivalent, or the term of any such extension is less than we request, our competitors or other third parties may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors or other third parties may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Any of the foregoing could materially harm our business, financial condition, results of operations and prospects.

We may license technology from third parties that may be subject to retained rights, including certain intellectual property discovered through government funded programs that is subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies.

Certain of our current licensors, and certain of our future licensors may retain, certain rights under the relevant agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself.

We currently collaborate, and our current and future licensors may also collaborate, with academic institutions to accelerate our research or development. We may acquire or license in the future intellectual property rights that have been generated with U.S. government funding or grants. If the U.S. government exercises its march-in rights in our existing or future intellectual property rights that are generated with U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to

contract with non-U.S. drug manufacturers for drugs covered by such intellectual property. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patent applications that we own or license or any patents we may obtain in the future;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by any such current or future pending patent applications that we own or license or any patents we may obtain in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;
- it is possible that the current or future pending patent applications we own or license now or in the future will not lead to issued patents;
- any issued patents that we own or license in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties, or may not provide us with any competitive advantages;
- others may have access to the same intellectual property rights licensed to us now or in the future on a nonexclusive basis;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent or other intellectual property rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patent rights;
- we may not develop additional proprietary technologies that are patentable;
- the patents or pending or future patent applications of others, if issued, or other intellectual property rights, may have an adverse effect on our business; and
- we may choose not to file for patent protection in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property.

Should any of these events occur, it could have a material adverse effect on our business, financial condition, results of operations and prospects.

We cannot ensure that patent rights relating to inventions described and claimed in our and our licensors' pending patent applications will issue or that patents based on our or our licensors' patent applications will not be challenged and rendered invalid and/or unenforceable.

We have pending provisional patent applications in the United States and pending patent applications under the PCT and in foreign countries in our portfolio relating to our research programs and product candidates. However, we cannot predict:

- the scope of protection of any patent issuing based on our or our licensors' patent applications;
- whether the claims of any patent issuing based on our or our licensors' patent applications will provide protection against competitors;
- whether or not third parties will find ways to challenge, narrow, invalidate or circumvent our or our licensors' patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our or our licensors' patents, if issued, and patent applications;
- whether we or our licensors will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof.

We cannot be certain that the claims in our current or future patent applications directed to our product candidates, as well as technologies relating to our research programs, will be considered patentable by the USPTO or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. The

biotechnology and pharmaceutical industries, including the fields of targeted radiopharmaceuticals, are intense, fast-moving and highly competitive. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim relevant to our business. There is no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position.

Even if the patents do issue based on our or our licensors' patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our or our licensors' future issued patents will be considered valid by courts in the United States or foreign countries. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be involved in lawsuits to protect or enforce any patents we obtain in the future or our future licensors' patents, which could be expensive, time consuming and unsuccessful. Further, any future issued patents we obtain or our current or future licensors' patents could be found invalid or unenforceable if challenged in court.

Competitors or other third parties may infringe, misappropriate or otherwise violate our intellectual property rights. To prevent such infringement or unauthorized use, we may be required to file infringement and other claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable or is not infringed. If we or any of our current or potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that such patent is invalid or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of sufficient written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity or unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our current or future licensors, and the patent examiners are unaware during prosecution. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our or our licensors' patent applications or any patents or patent applications we may obtain or license in the future, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our future patents or patent applications or those of our current or future licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all.

In addition, if the breadth or strength of protection provided by our or our licensors' patent applications or the patents and patent applications we may obtain or in-license in the future is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, rulings, motions and other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing any one of our future issued patents or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such an infringement claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our commercial success depends significantly on our ability to operate without infringing, misappropriating or otherwise violating the intellectual property and other proprietary rights, including patents, of third parties. Claims by third parties that we infringe, misappropriate, or otherwise violate their intellectual property or other proprietary rights, may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement, misappropriation or other violation of the intellectual property and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe, misappropriate, or otherwise violate patents, trade secrets or other intellectual property rights owned or controlled by third parties. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. If our defenses to such claims are unsuccessful, we could be liable for damages, which could be significant. Other entities may have or obtain patents, intellectual property rights or other proprietary rights that could limit our ability to make, use, sell, offer for sale, or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign-issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. The intellectual property landscape around our radiopharmaceutical product candidates is crowded, complex, and fast-moving, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property.

As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement, misappropriation or other violation of the patents or other intellectual property rights and proprietary rights of third parties. There could be certain third-party patent applications in this landscape we are unaware of that may, if issued as patents, be asserted to encompass aspects of our technology. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, may be confidential for 18 months or more after filing and can be revised before issuance, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. Furthermore, certain applications may remain confidential until a patent issues. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If a patent holder believes the manufacture, use, sale or importation of any of our product candidates infringes its patent, the patent holder may sue us even if we have licensed other patent protection for our technology. Moreover, we may face patent infringement claims from nonpracticing entities that have no relevant product revenue and against whom our owned or licensed patent portfolio may therefore have no deterrent effect. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;

- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties, including treble damages and attorneys' fees, if we are found to willfully infringe third-party intellectual property rights; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

We may choose to challenge the enforceability or validity of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-exam, IPR or PGR proceedings. We may also choose to challenge the validity of a third party's U.S. patent in federal court proceedings, however, to be successful, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Both USPTO and federal proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office, or EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office, then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or proprietary technologies.

It is possible that a third party may assert a claim of patent infringement directed at any of our product candidates. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates, treatment indications, or processes could subject us to significant liability for damages, including treble damages and attorneys' fees if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors or other third parties gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates, treatment indications, or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition, results of operations and prospects. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition to any of the foregoing events, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition, and prospects.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motion, and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, approved products, programs, or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

In addition, we rely on the protection of our trade secrets, including unpatented or unpatentable know-how, technology and other proprietary information to maintain our competitive position. Trade secrets and know-how can be difficult to protect. Although we have taken steps to protect our trade secrets and unpatented or unpatentable know-how, including entering into confidentiality agreements with third parties, and confidential information and invention assignment agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and 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. Further, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and process. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems; however, such systems and security measures may be breached, and we may not have adequate remedies for any breach. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult,

expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Competitors or third parties could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside the scope of our intellectual property rights. Moreover, third parties may still lawfully obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover them or that our trade secrets will be misappropriated or disclosed.

In addition to seeking patent protection for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach or other security incident) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and unpatented know-how can be difficult to trace, protect and enforce. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We seek to protect our potential trade secrets, proprietary know-how and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties. With our consultants, contractors and outside scientific collaborators, these agreements typically include invention assignment obligations. Although we have taken steps to protect our trade secrets and unpatented know-how, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets and unpatented know-how, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of skilled personnel from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. Because from time to time we expect to rely on third parties in the development, manufacture and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent 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 or other third party, our competitive position would be harmed, and our business, financial condition, results of operations and prospects could be materially adversely affected.

We may be subject to claims that we or our employees, consultants, or collaborators have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers or claims asserting ownership of what we regard as our own intellectual property.

Some of our employees, consultants, advisors and collaborators are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We have sought to enter into, and may in the future seek to enter into, non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, CDMOs, consultants, advisors, potential partners, and other third

parties. Although we try to ensure that our employees, consultants, advisors and collaborators do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions.

Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages, lead to a loss of valuable intellectual property rights or otherwise prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees. In addition, we may lose personnel as a result of such claims and any such litigation, or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates, which would have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property we regard as ours. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties to determine the ownership of what we regard as our intellectual property, or defend claims that they may bring against us. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual.

In addition, we or our licensors may in the future be subject to claims by former employees, collaborators, consultants or other third parties asserting an ownership right in our owned or licensed patent applications or future patents, patent applications, trade secrets or other intellectual property. For example, one of our licensors has inquired into whether they should be named as co-inventors for our pending patent applications relating to our Nectin-4 program, including [^{225}Ac]Ac-AKY-1189. Although we do not believe that anyone from the licensor made any contributions that rise to the level of inventorship on any of the claims that we are pursuing or plan to pursue, and we have had discussions with them regarding their inquiry, we cannot guarantee the final resolution of the matter. In some instances, litigation may be necessary to defend against claims challenging inventorship or ownership of our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees. An adverse determination in any such submission or proceeding 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 product candidates and technology, without payment to us, or could limit the duration of the patent protection covering our product candidates and proprietary technology. Such challenges may also result in our inability to develop, manufacture or commercialize our product candidates and proprietary technology without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patent rights, trade secrets or other intellectual property is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. 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. Any of the foregoing have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others.

We have entered into and may enter into in the future license agreements with others to advance our existing or future research or allow commercialization of our existing or future product candidates. If we fail to comply with our obligations under our intellectual property licenses, if the licenses are terminated, or if disputes regarding these licenses arise, we could lose significant rights that are important to our business. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, or defense of patent rights covering the technology that we license from third parties now

or in the future. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business or in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. It is also possible that our licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves or may not be conducted in accordance with our best interest. If we or our current or future licensors fail to prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected.

Our current or future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patent rights we in-license. If other third parties have ownership rights to our current or future in-licensed patent rights, they may be able to license such patent rights to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we can obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights to or from third parties or otherwise experience disruptions to our business relationships with our current and future licensors or licensees, we could lose license rights that are important to our business.

We are heavily reliant upon licenses from third parties to certain patent rights and proprietary technology that are important or necessary to the development of our proprietary technology. Further development of our proprietary technology may require us to enter into additional license or collaboration agreements. Our future licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates and proprietary technology in the future. Additionally, our current license agreements impose, and future agreements may impose, various development, diligence, commercialization and other obligations on us and require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses.

Disputes may arise between us and our current or future licensors or licensees regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor or licensee that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors or licensees and us and our partners; and
- the priority of invention of patented technology.

In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our proprietary technologies and product candidates.

The agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or

technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Despite our best efforts, our current or future licensors or licensees might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these licenses are terminated, or if the underlying patent rights fail to provide the intended exclusivity, competitors will have the freedom to seek regulatory approval of, and to market, products identical to ours, and we may be required to cease our development and commercialization of certain of our product candidates and proprietary technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our development programs may require or in the future require the use of additional intellectual property or proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party intellectual property or proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates on commercially reasonable terms or at all. Even if we are able to in-license any such necessary intellectual property, it could be on nonexclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and it could require us to make substantial licensing and royalty payments. The licensing and acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue or are already pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary.

More established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our product candidates, or to develop or license replacement candidates, all of which may not be feasible on a technical or commercial basis, and we may have to abandon development of the relevant program or product candidate, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our current and future trademarks and trade names, including our future registered trademarks and current or future unregistered trademarks, may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Moreover, our current or future trademark applications may not be allowed or may subsequently be opposed. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our trademarks or trade names. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. If we assert trademark infringement claims, a court may determine that the trademarks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we may propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

The use of new and evolving technologies, such as AI, in our operations may require us to expend material resources and may present risks and challenges that can impact our business, including by posing security and other risks to our confidential information, proprietary information and personal information, any of which may result in reputational harm and liability, or otherwise adversely affect our business.

We may choose to integrate AI into our operations, and this innovation presents risks and challenges that could affect its adoption, and therefore our business. There are significant risks involved in utilizing AI and no assurance can be provided that the usage of AI will enhance our business or assist our business in becoming more efficient or profitable. The use of certain AI technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement and misappropriation. Other known risks of AI currently include inaccuracy, bias, toxicity, data privacy and cybersecurity issues, and data provenance disputes. In addition, AI may have errors or inadequacies that are not easily detectable. AI may also be subject to data herding and interconnectedness (i.e., multiple market participants utilizing the same data), which may adversely impact our business. If the data used to train AI or the content, analyses, or recommendations that AI applications assist in producing are or are alleged to be deficient, inaccurate, incomplete, overbroad or biased, our business, financial condition, and results of operations may be adversely affected.

Additionally, we expect to see increasing government and supranational regulation and ethical concerns related to AI use, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the EU's Artificial Intelligence Act, or the AI Act,—the world's first comprehensive AI law—entered into force on August 1, 2024 and, with some exceptions, will become effective 24 months thereafter. This legislation imposes significant obligations on providers and deployers of AI systems, and encourages providers and deployers of AI systems to account for certain ethical principles in their design, development and use of these systems. The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our technology and products to help ensure that AI is implemented in accordance with applicable laws and regulations and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. The legal landscape and subsequent legal protection for the use of AI remains uncertain, and development of the law in this area could impact our ability to enforce our proprietary rights or protect against infringing uses. If we do not have sufficient rights to use the data on which AI relies or to the outputs produced by AI applications, we may incur liability through the violation of certain laws, third-party privacy or other rights or contracts to which we are a party. Our use of AI applications may also, in the future, result in cybersecurity incidents that implicate the personal data of customers or patients. Any such cybersecurity incidents related to our use of AI applications could adversely affect our reputation and results of operations.

Our collaborators or other third-party service providers may also incorporate AI tools into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to intellectual property, data privacy and cybersecurity. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, or otherwise adversely impact our business.

Risks related to Employee Matters and Managing Growth

Our ability to develop our future product candidates for our future growth depends on retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management, scientific, and technical personnel, many of whom have been instrumental for us and have substantial experience with our radiopharmaceuticals, our discovery engine and development processes and capabilities, underlying technologies, and related product candidates. In particular, we are highly dependent on Matthew Roden, PhD, our Chief Executive Officer, Kyle D. Kuvalanka, our Chief Financial Officer, Shulamit Ron-Bigger, PhD, our Chief Operating Officer, Paul L. Feldman, PhD, our Chief Scientific Officer, Akos Czibere, MD, PhD, our Chief Medical Officer and Tyler Benedum, PhD, our Chief Technical Officer, as well as the other principal members of our management

and scientific teams. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

For us to successfully compete and grow, we must recruit, retain, and develop talent who can provide the necessary expertise across a broad spectrum of disciplines. In addition, we must develop, maintain and, as necessary, implement appropriate succession plans to ensure we have the necessary human capital capable of maintaining continuity in our business. Given the fact that these are novel and emerging fields, there is an inherent scarcity of experienced personnel in these fields. As we continue developing our pipeline, we will require personnel with medical, scientific, or technical qualifications specific to each program. The loss of key managers and senior scientists could delay our research and development activities. Despite our efforts to retain valuable employees, members of our management, scientific, and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance for any of our executives or other employees. The competition for qualified personnel in the biotechnology industry is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical, and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business.

In addition, our research and development programs, clinical operations and sales and marketing efforts depend on our ability to attract and retain highly skilled scientists, engineers, and sales professionals.

Competition for skilled personnel in our market is intense, and we have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. Failure to succeed in preclinical studies, clinical trials or applications for regulatory approval may make it more difficult to recruit or retain qualified personnel. Moreover, if we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business, financial condition, results of operations and prospects would be harmed.

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

We have experienced rapid growth since our inception in August 2020. We expect continued growth in the number of our employees and the scope of our operations, particularly to continue our planned clinical operations, preclinical and IND-enabling studies or studies approved by comparable foreign authorities, establish regulatory, quality, and manufacturing supply chain logistics and facility operations.

To manage our anticipated future growth, we will continue to seek 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 complexity 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.

In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining, and motivating new employees; managing our internal development efforts effectively, including the clinical and FDA, or comparable foreign regulatory authority, review process for [^{225}Ac]Ac-AKY-1189 and any current or future product candidates, while complying with our contractual obligations to third parties; and improving our operational, financial and management controls, reporting systems, and procedures.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors, and consultants to provide certain services, including strategic, financial, business development, and research and development services, as well as certain aspects of regulatory approval and manufacturing. There can be no assurance that the services of independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed or on reasonable terms, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants, CROs, CDMOs or CMOs is compromised for any reason, our preclinical or clinical trials may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of [^{225}Ac]Ac-AKY-1189 or any of our other current or future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new qualified employees and expanding our groups of consultants and contractors, we may experience delays or may not be able to successfully implement the tasks necessary to further develop and commercialize [^{225}Ac]Ac-AKY-1189 for any Nectin-4 expressing tumor and any future product candidates we develop and, accordingly, we may not achieve our research, development, and commercialization goals.

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

Our operations, and those of our CROs, CDMOs, CMOs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates on a patient-by-patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our insurance policies are expensive and protect us from only some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employee benefits liability, workers' compensation, clinical trial liability, cyber liability, and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

Risks related to our common stock

Our stock price may be volatile or may decline regardless of our operating performance, resulting in substantial losses for investors.

Our stock price has been, and is likely to remain, volatile and may fluctuate substantially as a result of a variety of factors, some of which are related in complex ways. The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors listed below and other factors describe in this "Risk factors" section:

- developments with respect to our pipeline, including the commencement, enrollment, or results of current and future preclinical studies and clinical trials;
- any delay in our clinical trials for [^{225}Ac]Ac-AKY-1189 for the treatment of locally advanced or metastatic UC and other Nectin-4 expressing tumors or any of our future product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including, without limitation, the issuance by the FDA of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a preclinical study or clinical trial, not to initiate a preclinical study or clinical trial or to terminate an existing preclinical study or clinical trial;
- adverse actions taken by regulatory agencies with respect to our preclinical studies or clinical trials, manufacturing supply chain or sales and marketing activities, including failure to receive regulatory approval of our future product candidates;
- changes in laws or regulations, including, but not limited to, preclinical study or clinical trial requirements for approvals;
- any adverse changes to our relationship with manufacturers or suppliers;
- manufacturing, supply or distribution shortages;
- our failure to commercialize approved products;
- changes in the structure of healthcare payment systems;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of [^{225}Ac]Ac-AKY-1189 or any of our current or future product candidates;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;

- variations in our results of operations;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or radiopharmaceuticals in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements made by us or our competitors of new product offerings, acquisitions, strategic relationships, joint ventures, or capital commitments;
- our inability to establish or maintain collaborations;
- our ability to effectively manage our growth;
- the size of our initial target markets;
- changes in the market valuations of similar companies;
- press reports, whether or not true, about our business;
- sales or perceived potential sales of our common stock by us or our stockholders in the future;
- overall fluctuations in the equity and credit markets;
- ineffectiveness of our internal controls;
- changes in accounting practices or principles;
- changes or developments in the global regulatory environment;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- general political, economic, industry and market conditions, including resulting impacts of the ongoing war between Russia and Ukraine and the escalating hostilities in the Middle East; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Future sales of our common stock in the public market could cause our common stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate. The lock-up agreements entered into in connection with our initial public offering in January 2026 will expire at the close of business on July 7, 2026. J.P. Morgan Securities LLC, BofA Securities, Inc., Leerink Partners LLC and TD Securities (USA) LLC, in their sole discretion, may permit our equity holders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, the shares of common stock will be eligible for sale in the public market. As of March 10, 2026, we had outstanding a total of 53,403,173 shares of common stock. Of these shares, 20,297,500 shares of our common stock were sold in the initial public offering, substantially all of which are freely tradable, without restriction, in the public market.

In addition, the holders of approximately 34,057,218 shares of our common stock, which includes all of the shares of common stock issuable upon the conversion of our outstanding shares of Class A common stock, or approximately 61.6% of our outstanding capital stock, have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders, subject to the lock-up agreements described above. Registration of these shares under the Securities Act of 1933, as amended, or the Securities Act, would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our Class A common stock has no voting rights. As a result, all matters submitted to our stockholders will be decided by the vote of holders of our common stock. Based on the beneficial ownership of our common stock as of March 10, 2026, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 56.2% of our outstanding voting stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders, if acting together, may be able to determine all matters requiring stockholder approval and they may have interests that differ from yours and may be adverse to your interests. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction.

We may not be able to satisfy listing requirements of Nasdaq or obtain or maintain a listing of our common stock on Nasdaq.

Since our common stock is listed on Nasdaq, we must meet certain financial and liquidity criteria to maintain such listing. If we violate Nasdaq's listing requirements, our common stock may be delisted. If we fail to meet any of Nasdaq's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of our stockholders' investment.

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 of the value of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value for our common stock, which is not certain.

If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the trading price or trading volume of our common stock could decline.

The trading market for our common stock is influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. If one or more of these analysts initiate research with an unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors, or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline. In addition, if we fail to the meet the forecasts published by these analysts, the trading price of our common stock would likely decline.

We are an "emerging growth company," and a "smaller reporting company," and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. We are also a "smaller reporting company," as defined in Rule 12b-2 under the Securities Exchange Act of 1934, or the Exchange Act. For as long as we continue to be an "emerging growth company," and a "smaller reporting company" we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies and smaller reporting companies, including:

- not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could be an "emerging growth company" for up to five years following the completion of our initial public offering in January 2026. Our status as an "emerging growth company" will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have more than $1.235 billion in annual revenue;
- the date we qualify as a "large accelerated filer," with at least $700 million of equity securities held by non-affiliates;

- the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or
- the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering.

Even after we no longer qualify as an emerging growth company, we may continue to qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, if we are a smaller reporting company with less than $100.0 million in annual revenue, we would not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We would cease to be a smaller reporting company if the market value of our common stock that is held by non-affiliates exceeds $250.0 million and we had annual revenues in excess of $100.0 million or if the market value of our common stock that is held by non-affiliates exceeds $700.0 million, each as determined on an annual basis.

If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for any new or revised accounting standards during the period in which we remain an "emerging growth company" (or we affirmatively and irrevocably opt out of the extended transition period); however, we may adopt certain new or revised accounting standards early. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

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

Global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, including most recently in connection with the ongoing war between Russia and Ukraine and the political, economic and social instability in Venezuela. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

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, scale back or discontinue the development and commercialization of [^{225}Ac]Ac-AKY-1189 or one or more of our future product candidates or delay our pursuit of potential in-licenses or acquisitions. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not succeed or survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Our amended and restated certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against us or our directors, officers, or employees.

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, any state court located within the State of Delaware, or if all such state courts lack jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom is the sole and exclusive forum for the following types of claims or causes of action under Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action asserting a breach of a fiduciary duty owed by any current or former director, officer or other employee, to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (v) any claim or cause of action as to which the Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us, or any of our directors, officers or other employees, that is governed by the internal affairs doctrine, or otherwise related to our internal affairs, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. Our amended and restated certificate of incorporation states that these choice of forum provisions do not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the

Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States are the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions, which costs could be borne by investors, and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees and may discourage these types of lawsuits. Furthermore, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, and such costs could be borne by investors.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer, or proxy contest difficult, thereby depressing the trading price of our common stock.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause by the affirmative vote of the holders of at least two-thirds of the voting power of all of our then outstanding capital stock entitled to vote thereon;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, requires approval by the holders of at least two-thirds of our then-outstanding capital stock entitled to vote thereon, voting together as a single class.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving

our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

General risk factors

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

As a public company, and particularly after we are no longer an emerging growth company or smaller reporting company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Securities Act, the Exchange Act, Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy, geopolitical tensions, including heightened risk of military conflict, political instability and escalation of hostilities in the Middle East, and in the global financial markets. A severe or prolonged economic downturn or additional global financial and political crises could result in a variety of risks to our business, including weakened demand for any product candidates we develop or our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers or other third parties and create import and export issues, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We face risks related to health epidemics, pandemics and other widespread outbreaks of contagious disease, which could significantly disrupt our operations, impact our financial results or otherwise adversely impact our business.

Significant outbreaks of contagious diseases and other adverse public health developments could have a material impact on our business operations and operating results. As a result of public health crises that may arise, we may experience disruptions that could adversely impact our operations, research and development, and as we continue developing, any preclinical studies, clinical trials and manufacturing activities we may conduct, some of which may include:

- delays or disruptions in research programs, preclinical studies, clinical trials or IND-enabling studies that we or our collaborators may conduct;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving and distributing, supplies of drug substance and drug product from our CMOs, to preclinical or clinical research sites or delays or disruptions in any preclinical studies or clinical trials performed by CROs;
- limitations imposed on our business operations by local, state or federal authorities to address a pandemic or similar public health crises; and
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations, and cybersecurity and data accessibility or security issues.

In addition, the trading prices for biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic and we may face similar volatility in our stock price. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, financial condition, our results of operations and prospects.

Our operations are vulnerable to interruption by disasters, terrorist activity, pandemics and other events beyond our control, which could harm our business.

We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major flood, power loss, terrorist activity, pandemics or other regional or global disasters and generally do not have a recovery plan for such events. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs.

Failure to establish and maintain effective internal control over financial reporting could adversely affect our business and if investors lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be negatively affected.

As a public company, we are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Although we are required to disclose changes made in our internal control over financial reporting on a quarterly basis, we are not required to make our first annual assessment of our internal control over financial reporting until our annual report on Form 10-K for the year ending December 31, 2026. However, as an emerging growth company and smaller reporting company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company or smaller reporting company. At such time, our independent registered public accounting firm would need to issue a report that is adverse in the event that there are material weaknesses in our internal control over financial reporting.

As a private company, we did not have any internal audit function. To comply with the requirements of being a public company, we have undertaken various actions, and will need to take additional actions, such as implementing numerous internal controls and procedures and hiring additional accounting or internal audit staff or consultants. Testing and maintaining internal controls can divert our management's attention from other matters that are important to the operation of our business and failure to establish and maintain effective internal control over financial reporting could adversely affect our business and if investors lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be negatively affected.

Our disclosure controls and procedures or internal controls and procedures may not prevent or detect all errors or acts of fraud.

As a public company, we must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. Under current law, U.S. federal net operating losses, or NOLs, incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such U.S. federal NOLs in taxable years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the federal law.

As of December 31, 2025, we had $45.8 million of U.S. federal NOLs and $40.8 million of state NOLs. Our U.S. federal NOLs can be carried forward indefinitely under current laws and the state NOLs begin to expire in 2041. Additionally, we continue to generate U.S. federal research and development, or R&D, credits, which generally may be carried forward to offset a portion of future tax liabilities, if any, subject to expiration of such credit carryforwards. Our NOL carryforwards and R&D credits are subject to review and possible adjustment by the U.S. and state tax authorities.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a cumulative change (by value) in its equity ownership by "5-percent shareholders" that is greater than 50 percentage points over a rolling three-year period, the corporation's ability to use its pre-change NOL carryforwards, R&D credits and certain other pre-change tax attributes to offset its post-change income or taxes may be limited. This could limit the amount of NOLs, R&D credit carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. Our recently completed initial public offering, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change. Subsequent ownership changes, some of which may be outside our control, and changes to the U.S. tax rules in respect of the utilization of NOLs, R&D credits and other applicable tax attributes carried forward may further affect the limitation in future years. We have not conducted any studies to determine annual limitations, if any, that could result from such ownership changes.

In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations, or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, and the IRA have all made many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. It is also possible that future legislation could have an adverse effect on our operations, cash flows and results of operations and contribute to overall market volatility. In addition, it is uncertain if and to what extent various states will conform to recent or newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse consequences. Our internal computer systems, or those of our third-party CROs, manufacturers, contractors or consultants, or current or future collaborators or other third parties, may fail or suffer security breaches or other unauthorized or improper access, which could result in a material disruption of our development programs or other adverse consequences.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store, handle, share, use, retain, safeguard, transmit, analyze and otherwise process large amounts of data, including, without limitation, proprietary business information, intellectual property, health information, personal information and other confidential information, or collectively, confidential information. We have also outsourced elements of our operations to third parties, and as a result we manage a number of CROs, manufacturers, third-party vendors and other contractors, consultants and collaborators who have access to such information. It is critical that we and these third parties process such confidential information in a manner to maintain the confidentiality and integrity of such information.

Despite the implementation of security measures, given the size and complexity of our internal information technology systems and those of our current and future CROs, manufacturers, third-party vendors and other contractors, consultants and collaborators, and the increasing amounts of confidential information that we and such parties maintain, such internal information technology systems are potentially vulnerable to breakdown or other damage, interruption or incident, including from service interruptions, system failures or malfunctions, information security threats, such as data breaches, damage from computer viruses, cyberattacks (such as the deployment of malware, denial-of-service attacks, ransomware attacks, supply chain attacks, and phishing and other social engineering attacks), unauthorized access, intentional or accidental actions or inaction by our employees, third-party vendors, contractors, consultants, business partners or other third parties that introduce vulnerabilities, natural disasters, terrorism, war, telecommunication and electrical failures and other compromises or disruptions.

While we have not experienced any material system failures, accidents, security breaches, intrusions or other incidents to date, if such an event were to occur, or be perceived to occur, and cause interruptions in our operations or result in any inadvertent or unauthorized disclosure of or access to personal information, protected health information, or other sensitive, confidential or proprietary information, it could compel us to comply with breach notification laws, subject us to mandatory remedial action or otherwise result in a material disruption of our programs and/or material liability and reputation harm. For example, the loss of data from preclinical studies or clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Undetected security breaches of our information technology systems could result in the theft of our proprietary chemical structures and fraudulent filing of patent claims by competitors that could limit our freedom to operate in

the future. To the extent that any disruption, security breach or other incident results in a loss of or damage to our data or applications, other data or applications relating to our technology, [^{225}Ac]Ac-AKY-1189 or other current or future product candidates, or those of our third-party vendors and other contractors and consultants, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of [^{225}Ac]Ac-AKY-1189 or other current or future product candidates could be compromised or delayed. Any of the foregoing could result in significant legal and financial exposure and reputational damage that could potentially have a material adverse effect on our business, financial condition, results of operations, and prospects. We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party service providers operate to collect, store, handle, share, use, retain, safeguard, transmit, analyze and otherwise process electronic information in our day-to-day operations. In connection with our discovery efforts, we may collect, store, handle, use or otherwise process a variety of personal information and data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data (such as personal information) or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by computer hackers, hostile foreign governments or agencies, industrial espionage, cyber criminals, organized crime affiliates, terrorist organizations, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud, ransomware, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats or other means to threaten data security, confidentiality, integrity and availability. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information and trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by HITECH), and international law (e.g., the EU GDPR or the UK GDPR) and may cause a material adverse impact to our reputation, affect our ability to use collected data, conduct new studies and potentially disrupt our business.

Some actors now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process confidential information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third-party service providers to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident, breach or other interruption, including as described above, we could experience adverse consequences. Although we may have contractual protections with our service providers, any actual or perceived security breach or other incident could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach. Any contractual protections we may have from our service providers may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain data privacy and cybersecurity obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and confidential information. While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures have been or will be effective.

We rely on our CROs, manufacturers, contractors, consultants, collaborators and other third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies, breaches or other incidents. We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use, access and protection of computers and other devices that may contain our confidential information. There can be no assurances that these measures have been or will be effective. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyberattacks or other security incidents described above which could result in losses described above, as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, lost revenue or other adverse consequences. Any failure by such third parties to prevent or mitigate security breaches or improper access to or other unauthorized disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches or other incidents, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and cybersecurity obligations and related practices. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and cybersecurity practices, or any event that affects our systems or third-party systems where information important to our business operations or commercial development is stored or otherwise processed, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

In addition to experiencing a security incident, third parties may gather, collect, infer or otherwise obtain confidential information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have developed and maintain an information security program designed to assess, identify, and manage risks from cybersecurity threats. As part of this program, we conduct periodic assessments of our assets to evaluate the effectiveness of applicable security controls. These assessments are informed by industry standard frameworks and include a review of our information security controls to assess cybersecurity maturity compared to our peers and other security awareness trainings.

We engage security technology vendors to assist with detecting potential threats to our information assets. In addition, we have implemented a cybersecurity third party risk management process to assess mission and business critical third parties for cyber risks and to assist the business in making risk-informed technology product and services decisions. Our practice is to perform due diligence, including the completion of security questionnaires and risk assessments, as appropriate, on third parties who maintain material data or information to help us evaluate and verify third party information security capabilities.

Our process designed to detect and respond to cybersecurity incidents that may represent a threat to the confidentiality, integrity or availability of our information assets is based on industry standards and best practices of peer companies. Our technology, procedures and key vendors with security responsibilities are designed to help contain, eradicate and recover from cybersecurity incidents in a timely manner. Senior management is informed about incidents that may have a significant impact on the business. Incidents are reviewed once they are resolved, and policies and controls are updated to help mitigate gaps. We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, including our operations, business strategy, results of operations, or financial condition. We face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. There can be no assurance, however, that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information. For more information, see Part I, Item 1A “Risk Factors— If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse consequences. Our internal computer systems, or those of our third-party CROs, manufacturers, contractors or consultants, or current or future collaborators or other third parties, may fail or suffer security breaches or other unauthorized or improper access, which could result in a material disruption of our development programs or other adverse consequences."

Governance

Our board of directors, in coordination with the audit committee, oversees our cybersecurity risk management. On a regular basis, the audit committee discusses our cybersecurity risk management program with our Chief Operating Officer and other members of senior management. The audit committee receives regular reports from the Chief Operating Officer regarding cybersecurity and information technology matters, including recent developments, evolving standards, vulnerability assessments, third-party and independent reviews, the threat environment, technology trends, and information security considerations relating to our peers and third parties. The full board of directors receives reports from the audit committee on its cybersecurity risk management activities, as well as updates from management regarding the Company’s cybersecurity program.

Our management team, led by our Chief Operating Officer, has primary responsibility for developing and managing our overall cybersecurity risk management program. The Chief Operating Officer oversees our internal information technology functions and supervises third-party cybersecurity vendors and consultants.

The Chief Operating Officer works collaboratively across the Company to implement and maintain a program designed to protect our information systems from cybersecurity threats and to respond promptly to cybersecurity incidents in accordance with our incident response and recovery plans. Cross-functional teams throughout the Company support these efforts by addressing cybersecurity risks and responding to incidents as they arise. Through ongoing communication with these teams and our third-party service providers, the Chief Operating Officer monitors the prevention, detection, escalation, mitigation, and remediation of cybersecurity threats and incidents and reports significant matters to the audit committee, as appropriate.

Item 2. Properties.

Our principal facilities consist of office and laboratory space. Our corporate headquarters is located in Boston, Massachusetts, where we lease and occupy approximately 17,944 square feet of such laboratory and office space at 17 Drydock Avenue, Suite 17-401, Boston, Massachusetts 02210. The current term of our lease expires in January 2033. We also lease an aggregate of 12,089 square feet of laboratory and office space in two facilities in Durham, North Carolina, under leases that expire in April 2027 and September 2026. We sublease approximately 1,332 square feet of such laboratory and office space.

We believe these facilities are adequate for the foreseeable future and that suitable additional space will be available as and when needed. To meet the future needs of our business, we may lease additional or alternate space. We believe that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising from the ordinary course of business. We record a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment by us is required to determine both probability and the estimated amount. We are not currently subject to any material legal or arbitration proceedings.

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 began trading on the Nasdaq Global Select Market under the symbol "AKTS" on January 9, 2026. Prior to that time, there was no public market for our common stock.

Holders of our Common Stock

As of March 10, 2026, there were approximately 69 stockholders of record of shares of our common stock and 4 holders of shares of our Class A common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. Payment of cash dividends, if any, in the future will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Equity Securities

Between January 1, 2025 and December 31, 2025, we issued to certain of our employees and directors options to purchase an aggregate of 784,343 shares of our common stock at a weighted average exercise price of $10.59 per share under our 2020 Equity Incentive Plan, or the 2020 Plan. On January 8, 2026, we issued to certain of our employees and directors options to purchase an aggregate of 1,720,277 shares of our common stock at an exercise price per share equal to $18.00 under our 2026 Equity Incentive Plan, or the 2026 Plan. The offers, sales and issuances of the securities described in this paragraph were deemed to be exempt from registration either under Rule 701 promulgated under the Securities Act, or Rule 701, in that the transactions were under compensatory benefit plans and contracts relating to compensation. The recipients of such securities were our employees, directors or consultants and received the securities under the 2020 Plan or the 2026 Plan, as applicable. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about our company. We filed a registration statement on Form S-8 (File No. 333-292679) under the Securities Act on January 12, 2026 to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to the 2020 Plan and 2026 Plan.

On January 12, 2026, immediately prior to the closing of our initial public offering, or the IPO, all of our outstanding shares of convertible preferred stock automatically converted into 34,057,218 shares of our common stock and 1,872,829 shares of our Class A common stock. The issuance of such common stock and Class A common stock upon conversion of the convertible preferred stock was exempt from the registration requirements of the Securities Act pursuant to Section 3(a)(9) thereof, involving an exchange of securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Annual Report

Use of Proceeds from our Initial Public Offering

On January 8, 2026, the SEC declared effective our registration statement on Form S-1 (File No. 333-292283), as amended, or the Registration Statement, filed in connection with our IPO. Pursuant to the Registration Statement, we registered the offer and sale of 20,297,500 shares of our common stock with a maximum aggregate offering price of approximately $365.4 million. J.P. Morgan Securities LLC, BofA Securities, Inc., Leerink Partners LLC and TD Securities (USA) LLC acted as representatives of the underwriters for the IPO. We received net proceeds of $335.3 million from the sale of 20,297,500 share of common stock at a price of $18.00 per share, which included 2,647,500 shares of common stock sold pursuant to the underwriters' full exercise of their option to purchase additional shares, after deducting offering costs payable by us of $4.5 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b) of the Securities Act on January 9, 2026. We are holding a significant portion of the balance of the net proceeds in money market funds.

Issuer Repurchases of Equity Securities

None.

Item 6. [Reserved]

Not applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes and other financial information included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. See "Special Note Regarding Forward-Looking Statements." As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report and "Cautionary Note Regarding Forward-Looking Statements", our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

Overview

We are a clinical-stage oncology company focused on expanding the breakthrough potential of targeted radiopharmaceuticals to large patient populations, including those not addressed by existing platform technologies. The field of targeted radiopharmaceuticals is currently led by two marketed products that illustrated transformative survival outcomes and quality of life benefits can be conferred by delivering radioisotopes to solid tumors. These leading products, which target prostate specific membrane antigen or somatostatin-2 receptor, are each currently approved in only one tumor type, but in those indications, have seen considerable commercial uptake and have become fundamental pillars of cancer treatment. Despite these advances, we believe that the field of radiopharmaceuticals is still in its infancy, with many emerging companies still primarily focused on these same two targets. In contrast, we see a significant opportunity to broaden the cancer patient populations benefiting from targeted radiopharmaceuticals by developing next-generation technologies that expand the scope of tumor targets for which it is possible to safely deliver a powerful payload of an alpha-emitting radioisotope. To ensure patient demand is reliably met, we are also establishing efficient end-to-end supply, with a combination of critical internal capabilities paired with experienced external vendors. Through these efforts, we seek to maximize clinical utility across multiple indications in multiple tumor types, and to expand the commercial uptake of radiopharmaceuticals beyond the traditional nuclear medicine setting and into the more expansive clinical oncology setting.

Since our inception in August 2020, we have devoted substantially all of our resources to developing our miniprotein radioconjugate platform, identifying and developing our product candidates and programs, establishing and protecting our intellectual property, conducting research and development activities, building our supply chain and manufacturing capabilities, organizing and staffing our company, raising capital and providing general and administrative support for these operations. We do not have any products approved for commercial sale and have not generated any revenues from product sales. We have funded our operations primarily with proceeds from the issuance and sale of our redeemable convertible preferred stock and upfront payments from a Research and Collaboration Agreement, the Collaboration Agreement, with Eli Lilly and Company, or Eli Lilly, and have received aggregate net proceeds of $345.5 million from the sale of our redeemable convertible preferred stock, $60.0 million in upfront payments upon entering into the Collaboration Agreement, and $1.0 million upon achieving the first development milestone under the Collaboration Agreement. In January 2026, we completed our initial public offering, or the IPO, and raised aggregate net proceeds of $335.3 million from the sale of 20,297,500 shares of common stock, which included 2,647,500 shares of common stock sold pursuant to the underwriters' full exercise of their option to purchase additional shares.

We have incurred significant operating losses in every year since inception and we expect to continue to incur substantial losses for the foreseeable future. Our ability to generate revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. As of December 31, 2025, we had an accumulated deficit of $156.6 million and our net losses were $63.7 million and $44.0 million for the years ended December 31, 2025 and 2024, respectively. We expect our expenses and operating losses will increase substantially as we:

- advance our lead product candidate, [^{225}Ac]Ac-AKY-1189 for Nectin-4 expressing tumors, through clinical trials;
- seek regulatory approval to commence clinical trials for [^{225}Ac]Ac-AKY-2519 for B7-H3 expressing tumors;
- continue IND-enabling preclinical studies for our other programs;
- continue to advance our miniprotein radioconjugate platform;
- acquire or in-license other product candidates, targeting molecules and technologies;
- conduct preclinical studies and clinical trials for our other product candidates;
- seek to identify additional product candidates;
- continue to utilize third-parties to manufacture our lead product candidate;
- scale up our supply of ^{225}Ac and other radioisotopes;
- continue to expand manufacturing capabilities through additional in-house facilities and expertise, as well as additional third party contractors to enable global commercial scale;

- seek regulatory approval of product candidates that successfully complete clinical development;
- expand our operational, legal, compliance, financial, and management information systems and increase personnel, including personnel to support our preclinical and clinical development, manufacturing, and future commercialization efforts as well as to support our operations as a public company;
- obtain, expand, maintain, defend and enforce our intellectual property portfolio;
- contract with manufacturing sources for preclinical and clinical development of any future product candidates we may develop and commercial supply with respect to any such product candidates that receive regulatory approval;
- undertake pre-commercial activities to enhance commercialization prospects for any current or future product candidates that may obtain regulatory approval; and
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval.

In addition, we have several clinical development, regulatory, and commercial milestones, as well as royalty payment obligations under our licensing arrangements. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our ongoing and planned clinical trials and our expenditures on other research and development activities.

We do not have any products approved for sale and have not generated any revenue from product sales. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our current and any future product candidates, which we expect will take a number of years or may never occur. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings or other capital sources, including collaborations, licenses or other strategic arrangements. See "*—Liquidity and capital resources*." We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates, or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Due to the numerous risks and uncertainties associated with the development of radiopharmaceutical candidates, we are unable to accurately predict the timing or amount of increased expenses or the timing of when, or if, we will be able to achieve or maintain profitability. Even if we generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of December 31, 2025, we had cash, cash equivalents and marketable securities of $226.8 million. Based upon our current operating plans, we believe that our existing cash, cash equivalents and marketable securities, together with the net proceeds of approximately $335.3 million from our IPO completed in January 2026, will be sufficient to fund our operations into 2029. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See the sections titled "*—Liquidity and capital resources*" and "*Risk Factors*" included elsewhere in this Annual Report.

License and collaboration agreements

We may incur contingent regulatory and development milestones, commercial milestones and royalty payments that we are required to make under our license and collaboration agreements, in which the amounts to be paid by us are not fixed or determinable at this time. For a more detailed description of these agreements, see the section titled "*Business—License and collaboration agreements*" and Notes 11 and 12 to our consolidated financial statements included elsewhere in this Annual Report.

Blaze Bioscience license agreement

On July 22, 2021, we entered into a Discovery, License and Option Agreement, or the Blaze Agreement, as amended on March 3, 2022, May 20, 2022 and December 19, 2022, with Blaze Bioscience Inc., or Blaze, pursuant to which we granted to each other certain exclusive and non-exclusive licenses and an option to license Blaze's platform technology to use in conducting certain research and development activities. We made a one-time non-refundable upfront payment of $1.8 million to Blaze, as partial consideration for the rights and licenses granted to us under the Blaze Agreement. We paid an additional one-time payment of $0.2 million in connection with the December 19, 2022 amendment. The Blaze Agreement required us to make specified non-refundable, non-creditable milestone payments of up to $0.7 million per collaboration target as well as royalty payments on a product-by-product basis until the later of (a) the date of expiration of the last-to-expire valid claim covering such collaboration target, or (b) ten years following the date of the first commercial sale of such collaboration target. None of the milestones had been achieved prior to termination.

Upon execution of the Blaze Agreement, we also issued to Blaze, warrants, or the Preferred Stock Warrants, to purchase 2,000,000 shares of partner preferred stock, or the Partner Preferred Stock, as a partial consideration for the rights granted by Blaze to us. The Preferred Stock Warrants represent an additional upfront payment and the initial fair value of the Preferred Stock Warrants was $0.6 million. See Note 11 to our consolidated financial statements included elsewhere in this Annual Report. In connection with the amendment on May 20, 2022, we replaced the original terms of the Preferred Stock Warrants with revised vesting criteria, related to the achievement of development and regulatory milestones. As of December 31, 2023, 250,000 shares of the Preferred Stock Warrants were vested.

In March 2024, we notified Blaze of our decision to terminate the Blaze Agreement and Blaze exercised the Preferred Stock Warrants for 250,000 shares of Partner Preferred Stock upon payment of nominal consideration. The remaining unvested Preferred Stock Warrants were cancelled upon the notice of termination.

Institute for Protein Innovation, Inc. license agreement

On November 1, 2021, we entered into an exclusive license agreement, the IPI Agreement, with the Institute for Protein Innovation, Inc., or IPI, pursuant to which IPI granted us an exclusive, worldwide license, with the right to sublicense (subject to certain conditions), under certain of IPI's patents and know-how related to certain binder proteins, targeting up to 14 target proteins, including Nectin-4, to research, develop, make, have made, and commercialize certain products. We made an initial upfront payment of $0.2 million and will make annual payments of less than $0.1 million on each anniversary up to the date of the first commercial sale of the first licensed product in order to retain the licenses, pursuant to which we have paid an aggregate of $0.2 million through December 31, 2025. The IPI Agreement requires us to pay up to an aggregate of $24.0 million upon achievement of certain regulatory and development milestones. In addition, if we successfully commercialize a licensed product under the IPI Agreement, we are required to pay low single-digit royalties on net sales on a product-by-product and country-by-country basis, subject to specified reductions, until the later of (a) the expiration of the last to expire valid claim covering the manufacture, use or sale of such licensed product in such country or (b) ten years after the first licensed product sale in such country. The royalties are subject to specified and capped reductions for payments owed to third parties for additional rights necessary to commercialize licensed products and will terminate upon the last to expire royalty term. As of December 31, 2025, no such milestones have been achieved. For further details see the sections titled "*Business—License and collaboration agreements*" included elsewhere in this Annual Report.

TRIUMF license agreement

On July 21, 2022, we and TRIUMF Inc., a Canadian non-profit, or TRIUMF, TRIUMF Innovations, Inc., a Canadian non-profit, the University of British Columbia, and BC Cancer, a provincial health services authority, entered into a License Agreement, the TRIUMF License. Pursuant to the TRIUMF License, TRIUMF, the University of British Columbia and BC Cancer, or the Licensors, granted us a non-exclusive, worldwide license, with the right to sublicense (subject to certain conditions), under certain patents and know-how related to the Licensors' chelator technology to make, use, sell, offer for sale, import, and export certain radiopharmaceutical products for the diagnosis, treatment, amelioration, and prevention of human diseases and conditions. None of our product candidates currently incorporate, or rely on, the licensed patents and know-how from the TRIUMF License.

We paid an initial license fee of $0.1 million upon execution of the TRIUMF License. The TRIUMF License requires us to pay up to an aggregate of $2.0 million upon achievement of certain regulatory and development milestones. We are also obligated to pay low single digit royalties on net sales of licensed products, on a product-by-product basis. For licensed products not covered by a valid claim of a licensed patent, our royalty obligation terminates on the tenth anniversary of the first commercial use of such licensed product in each country. As of December 31, 2025, no such milestones have been achieved. For further details see the sections titled "*Business—License and collaboration agreements*" included elsewhere in this Annual Report.

University of Minnesota license agreement

On March 3, 2023, we entered into an exclusive license agreement, the Minnesota License, with Regents of the University of Minnesota, or the University of Minnesota, under which we licensed certain rights to the licensed patents of a known target-binding miniprotein, the Licensed Patents, for commercialization. We made an initial payment of $0.1 million and paid an annual license fee of less than $0.1 million throughout the term of the Minnesota License, pursuant to which we have paid an aggregate of $0.4 million through December 31, 2025. In July 2025, we provided notice to the University of Minnesota to terminate the Minnesota License and paid the $10,000 early termination fee, with an effective termination date of September 9, 2025. None of our product candidates incorporate, or rely on, the patents and know-how from the Minnesota License. For further details see the sections titled "*Business—License and collaboration agreements*" included elsewhere in this Annual Report.

Eli Lilly and Company research and collaboration agreement

In May 2024, we entered into the Collaboration Agreement with Eli Lilly to generate anticancer radiopharmaceuticals using our novel miniprotein technology platform. Pursuant to the Collaboration Agreement, we granted Eli Lilly an exclusive (even as to us and our affiliates), royalty-bearing, worldwide license, with the right to sublicense, to certain of our patents and other intellectual property rights to exploit certain compounds and therapeutic or diagnostic products that contain such compounds solely as products that contain a radioactive isotope. We also granted Eli Lilly a non-exclusive, royalty-bearing, worldwide license, with the right to sublicense, to the intellectual property necessary or useful to exploit the licensed compounds and licensed products solely as products that contain a radioactive isotope and a non-exclusive, fully paid-up license, with the right to sublicense, to exploit certain other intellectual property developed under the Collaboration Agreement for any and all purposes (subject to certain limitations). In addition, we and Eli Lilly agreed to negotiate in good faith to enter into a separate agreement in the event the parties agree that the clinical development of a licensed compound requires, or would be benefited by, a license to one of our other compounds. Eli Lilly may, at any time in its sole discretion and without cause, terminate the Collaboration Agreement on a collaboration target-by-collaboration target or region-by- region basis (or any combination thereof) upon 60 days' prior written notice to us.

Under the Collaboration Agreement, Eli Lilly may designate a specified number of initial collaboration targets, with the right to substitute other targets. We will be responsible for research activities through initial human imaging studies for a lead candidate for each selected target, and Eli Lilly will thereafter be responsible for regulatory filings, clinical development and commercialization activities worldwide. There is a separate research plan for each collaboration target, and our development costs are capped, on a research plan-by-research plan basis. Eli Lilly will reimburse our reasonable out-of-pocket costs and full-time equivalent costs incurred in excess of the cap.

Eli Lilly paid us an upfront license fee of $60.0 million as a nonrefundable cash payment upon execution of the Collaboration Agreement. The Collaboration Agreement requires Eli Lilly to pay up to an aggregate of $525.0 million upon achievement of certain research development, regulatory and commercial launch milestones and up to an aggregate of $630.0 million upon achievement of certain sales milestones. As of December 31, 2025, one development milestone under the Collaboration Agreement totaling $1.0 million was achieved. In addition, if Eli Lilly successfully commercializes a therapeutic or diagnostic product under the Collaboration Agreement, Eli Lilly is required, unless earlier terminated, to pay us tiered royalties of up to 10% based on annual net sales, on a product-by-product and country-by-country basis, subject to specified reductions, until the later of the expiration of licensed patent rights in a country, expiration of regulatory exclusivity, or ten years after the first product sale in such country. The Collaboration Agreement requires Eli Lilly to use commercially reasonable efforts to develop and commercialize a licensed product from a research program in certain markets and through satisfaction of certain criteria. For further details see the sections titled "*Business—License and collaboration agreements*" included elsewhere in this Annual Report.

Components of results of operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future, if ever. Substantially all of our revenue to date has been derived from the work performed under the Collaboration Agreement.

If our development efforts for our current or future product candidates are successful and result in regulatory approval or if we enter into additional license or collaboration agreements with third parties, we may generate revenue in the future from product sales, payments from such license or collaboration agreements, or any combination thereof. We cannot predict if, when or to what extent we will generate revenue as we may never succeed in obtaining regulatory approval for any of our product candidates. If we fail to complete preclinical and clinical development of our current or future product candidates or fail to obtain regulatory approval for any that successfully complete clinical trials, our ability to generate future revenues, and our results of operations and financial position would be adversely affected.

Operating expenses

Research and development expenses

We recognize research and development expenses in the periods in which they are incurred. Research and development expenses consist primarily of employee-related costs and other internal and external costs associated with our discovery and development efforts and the preclinical development of our current and future product candidates. In particular, our research and development expenses include:

- employee-related costs, including salaries, bonuses, benefits and stock-based compensation for employees engaged in research and development functions;
- the costs to acquire in-process research and development with no alternative future use acquired in an asset acquisition;
- external expenses, including expenses incurred under arrangements with third parties, such as contract research organizations, or CROs, contract development and manufacturing organizations, or CDMOs, consultants and our scientific advisors;
- the cost of manufacturing our product candidates, including costs for laboratory supplies, research materials and reagents;
- license and collaboration fees, including any milestone-based payments;
- facility costs, depreciation and other expenses, which include direct and allocated expenses; and
- the cost of obtaining and maintaining patent and trade secret protection for our product candidates.

We track direct external research and development expenses by stage of program, clinical or preclinical. We expect to report external research and development expenses for each clinical drug candidate following development candidate designation. Our internal research and development expenses are deployed across multiple programs and, as such, are not separately tracked. Significant judgments and estimates are made in determining the accrued, or prepaid expense balances at the end of any reporting period.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we advance our product candidates into and through clinical development and as we continue to develop additional product candidates. We expect to fund our research and development expenses from our current cash, cash equivalents, investments in marketable securities, and a combination of public and private equity offerings, debt financings, or other sources of capital, which may include additional collaborations with other companies, marketing, distribution, or licensing arrangements with third parties, or other similar arrangements.

General and administrative expenses

General and administrative expenses consist primarily of employee-related costs, including salaries, bonuses, benefits, and stock-based compensation expenses for personnel in executive, finance, accounting, human resources, and other administrative functions. General and administrative expenses also include professional and consulting expenses, including legal fees relating to patent, intellectual property, and corporate matters, professional fees for accounting, audit, and consulting services, and facility and depreciation expenses, including expenses for rent, insurance expenses, and other operating costs not included in research and development. We recognize general and administrative expenses in the periods in which they are incurred.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our expansion of the business. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, compliance, and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

Other income, net

Interest income

Other income, net consists of interest earned, the accretion or amortization of discount or premiums on our cash equivalents and investments in marketable securities, income (expense) associated with the change in fair value of the Preferred Stock Warrant Liability, and realized and unrealized foreign currency transaction losses.

Income taxes

Since our inception, we have not recorded any income tax benefits or expense for the net losses we have incurred in each period or for our earned research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credits will not be realized. As of December 31, 2025, we had net operating loss carryforwards, or NOLs, for federal and state income tax purposes of $45.8 million and $40.8 million, respectively. The federal NOLs are not subject to expiration and the state NOLs begin to expire in 2041. These loss carryforwards are available to reduce future federal taxable income, if any. As of December 31, 2025 and 2024, we have recorded a full valuation allowance against our net deferred tax assets.

Results of operations

Comparison of the years ended December 31, 2025 and 2024

The following table summarizes our results of operations (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Revenue:			
Collaboration revenue	$ 6,497	$ 1,487	$ 5,010
Total revenue	6,497	1,487	5,010
Operating expenses:			
Research and development	67,451	40,954	26,497
General and administrative	13,730	12,583	1,147
Total operating expenses	81,181	53,537	27,644
Loss from operations	(74,684)	(52,050)	(22,634)
Total other income, net	10,953	8,070	2,883
Net loss	$ (63,731)	$ (43,980)	$ (19,751)

Revenue

Collaboration revenue was $6.5 million and $1.5 million for the years ended December 31, 2025 and 2024, respectively, driven by a full year of revenue recognized in 2025 from our Collaboration Agreement with Eli Lilly, which was entered into in May 2024 and is recognized over time using the cost incurred input method.

Research and development expenses

The following table summarizes our research and development expenses (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Direct external research and development expenses by program:			
Discovery and development	$ 12,629	$ 8,787	$ 3,842
[^{225}Ac]Ac-AKY-1189	11,443	5,988	5,455
[^{225}Ac]Ac-AKY-2519	7,311	385	6,926
Unallocated research and development expenses:			
Employee-related (including stock-based compensation)	22,921	14,046	8,875
Facility, lab and depreciation	11,529	10,111	1,418
Other research and development related costs	1,618	1,637	(19)
Total research and development expenses	$ 67,451	$ 40,954	$ 26,497

Research and development expenses were $67.5 million for the year ended December 31, 2025, compared to $41.0 million for the comparable prior year period. The increase of $26.5 million was primarily due to the following:

- $8.9 million increase primarily driven by an increase in employee-related costs (including stock-based compensation) attributable to our increased headcount to support the advancement of our clinical development programs and manufacturing;
- $6.9 million increase in direct costs associated with advancing [^{225}Ac]Ac-AKY-2519 through IND-enabling studies;
- $5.5 million increase in direct costs for [^{225}Ac]Ac-AKY-1189 related to the initiation of and ongoing operations of our Phase 1b clinical trial for this program;
- $3.8 million increase in discovery and development costs relating to direct external research as we continue to identify and develop product candidates; and
- $1.4 million increase in facility, lab and depreciation costs primarily related to an increase in laboratory equipment as a result of our expansion of laboratory space and an increase in software subscriptions.

General and administrative expenses

The following table summarizes our general and administrative expenses (in thousands):

	Year Ended December 31,		
	2025	2024	Change
Employee-related expenses (including stock-based compensation)	$ 7,676	$ 6,143	$ 1,533
Professional and consulting expenses	4,922	5,164	(242)
Facility, depreciation, and other	1,132	1,276	(144)
Total general and administrative expenses	$ 13,730	$ 12,583	$ 1,147

General and administrative expenses were $13.7 million for the year ended December 31, 2025, compared to $12.6 million for the comparable prior year period. The increase of $1.1 million was primarily due to the following:

- $1.5 million increase primarily driven by an increase in employee-related expenses (including stock-based compensation) attributable to our increased headcount, partially offset by;
- $0.2 million decrease in professional and consulting expenses driven by a decrease in accounting and legal fees; and
- $0.2 million decrease in facilities expense related to the expiration of a sublease in June 2025.

Other income, net

Other income, net was $11.0 million for the year ended December 31, 2025, compared to $8.1 million for the comparable prior year period. The increase of $2.9 million was primarily driven by an increase in interest income earned due to higher average balances in cash equivalents and marketable securities in the year ended December 31, 2025, compared to the comparable prior year period.

Liquidity and capital resources

Sources of liquidity

Since our inception, we have incurred significant operating losses. We have not generated any revenue from product sales and we do not expect to generate revenue from sales of products in the near term, if at all. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates into and through clinical development and as we continue to develop additional product candidates. As such, we expect our research and development and general and administrative costs will continue to increase significantly, including the costs associated with operating as a public company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings or strategic agreements.

To date, we have funded our operations primarily with proceeds from the issuance and sale of our redeemable convertible preferred stock and the Collaboration Agreement with Eli Lilly. As of December 31, 2025, we had raised aggregate net proceeds of $345.5 million through the sale and issuance of our redeemable convertible preferred stock and received $60.0 million in upfront payments and $1.0 million from the achievement of the first milestone under the Collaboration Agreement with Eli Lilly. As of December 31, 2025, we had cash, cash equivalents and marketable securities of $226.8 million.

In January 2026, we raised aggregate net proceeds of $335.3 million from the sale of shares of common stock in our initial public offering.

Cash flows

The following table sets forth a summary of the net cash flow activity (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash (used in) provided by operating activities	$ (64,127)	$ 14,762
Net cash provided by (used in) investing activities	65,964	(190,400)
Net cash (used in) provided by financing activities	(1,212)	183,284
Net increase in cash, cash equivalents and restricted cash	$ 625	$ 7,646

Operating activities

Net cash used in operating activities was $64.1 million for the year ended December 31, 2025, primarily consisting of our net loss of $63.7 million and net changes in operating assets and liabilities of $3.4 million, offset by non-cash charges of $2.8 million related to accretion of investment discounts, stock-based compensation and depreciation.

Net cash provided by operating activities was $14.8 million for the year ended December 31, 2024, primarily consisting of net changes in operating assets and liabilities of $59.0 million, primarily driven by an increase in deferred revenue in connection with the Collaboration Agreement of $58.5 million, partially offset by our net loss of $44.0 million, and $0.2 million of non-cash charges related to stock-based compensation, depreciation, and accretion of investment discounts.

Investing activities

Net cash provided by investing activities was $66.0 million for the year ended December 31, 2025, primarily consisting of maturities of marketable securities of $269.4 million, partially offset by purchases of marketable securities and property and equipment of $193.8 million and $9.6 million, respectively.

Net cash used in investing activities was $190.4 million for the year ended December 31, 2024, primarily consisting of the purchases of marketable securities and property and equipment of $288.4 million and $2.9 million, respectively, partially offset by maturities of marketable securities of $100.9 million.

Financing activities

Net cash used in financing activities was $1.2 million during the year ended December 31, 2025, primarily consisting of payments of deferred offering costs of $1.5 million, partially offset by proceeds received from the exercise of common stock options of $0.3 million.

Net cash provided by financing activities was $183.3 million during the year ended December 31, 2024, primarily consisting of proceeds from the issuances of Series A-1 redeemable convertible preferred stock and Series B redeemable convertible preferred stock of $10.0 million and $175.0 million, respectively, and the exercise of common stock options of $0.2 million, partially offset by payments of deferred offering costs of $1.5 million and issuance costs relating to the Series A-1 and Series B financings of $0.3 million.

Future funding requirements

As of December 31, 2025, we had cash, cash equivalents and marketable securities of $226.8 million. Based upon our current operating plans, we believe that the net proceeds from our initial public offering, together with our cash, cash equivalents and marketable securities as of December 31, 2025, will be sufficient to fund our operations into 2029. We have based this estimate on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we expect.

We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates into and through clinical development and as we continue to develop additional product candidates. In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. We may also require additional capital to pursue additional research and collaboration agreements.

Because of the numerous risks and uncertainties associated with research, development, and commercialization of pharmaceutical product candidates, we are unable to estimate the amount of our future working capital requirements. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs related to the clinical development of [^{225}Ac]Ac-AKY-1189 for Nectin-4 expressing tumors;
- the scope, progress, results and costs of discovery, preclinical development and planned clinical trials for our future product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the cost of advancing and furthering our miniprotein radioconjugate platform;
- the costs of establishing, operating and maintaining our manufacturing facility, or securing other manufacturing arrangements for clinical-supply and commercial production;
- the cost and availability of sufficient supply of ^{225}Ac and other radioisotopes;
- the achievement of milestones or occurrence of other developments that trigger payments by us or our collaborators under any current or future collaboration agreements;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;

- the emergence of competing therapies for oncology indications and other adverse market developments;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining, protecting, defending and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory clearances to market [^{225}Ac]Ac-AKY-1189 for any Nectin-4 expressing tumors or any future product candidates.

We have no committed sources of capital. Until such time, if ever, as we can generate substantial product revenue to support our cost structure, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, potentially including collaborations, licenses or other strategic arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. In addition, debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through a strategic agreement, we may have to grant rights to develop and market our current and future product candidates even if we would otherwise prefer to develop and market such product candidates ourselves. Our failure to raise capital or enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise additional capital or obtain adequate funding when needed or on acceptable terms, we may be required to delay, scale back, or discontinue our research, 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.

Contractual obligations and commitments

Royalty transfer agreement

In August 2020, we entered into a royalty transfer agreement, or the Royalty Transfer Agreement, with MPM Oncology Charitable Foundation, Inc., or MPM Charitable Foundation, an affiliate of a stockholder holding more than 5% of our total outstanding stock, and the UBS Optimus Foundation, or UBS, and together with MPM Charitable Foundation, the Charitable Foundations. Pursuant to the Royalty Transfer Agreement, we will pay 0.5% of our annual global net sales to each of the Charitable Foundations, for a total of 1.0% of net sales, subject to customary reductions, for products that incorporate or utilize intellectual property that was discovered or developed by us prior to our initial public offering. Our payment obligations for each product will continue on a country-by-country basis upon the later of the twelfth anniversary of the first commercial sale of our product in such country or the expiration of the last to expire of certain patents owned or controlled by us covering such products in such country.

Our payment obligations to MPM Charitable Foundation will terminate immediately upon the authorization of the MPM Charitable Foundation's board of directors (or similar body) or upon the winding up or dissolution of MPM Charitable Foundation. Our payment obligations to UBS will terminate immediately upon the winding up of Oncology Impact Fund 2, L.P., a Cayman Islands exempted limited partnership, which is associated with MPM Charitable Foundation.

Leases

As of December 31, 2025, we had future minimum operating lease payment obligations under non-cancellable leases of $16.3 million related to leases we have recognized on our consolidated balance sheets, which are due over the following 6.87 years.

License agreements

Our agreements with certain third parties to license intellectual property include potential milestone fees, sublicense fees and royalty fees. The milestone fees are dependent upon the development of products using the intellectual property licensed under the arrangements and contingent upon the achievement of development or regulatory approval milestones, as well as commercial milestones. These potential obligations are contingent upon the occurrence of future events and the timing and likelihood of such potential obligations are not known with certainty. For further information regarding these agreements, please see the section titled "*Business—License and collaboration agreements,*" included elsewhere in this Annual Report.

Purchase and other obligations

We enter into contracts in the normal course of business with CROs and other third-party vendors for preclinical and commercial supply manufacturing, support for pre-commercial activities, research and development activities, and other services and products for our operations. These contracts are generally cancelable upon written notice. For additional information on our contractual obligations and commitments please see Note 13 to our consolidated financial statements included elsewhere in this Annual Report.

Critical accounting estimates

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included elsewhere in this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue recognition

In May 2024, we entered into the Collaboration Agreement. We apply the revenue recognition guidance in accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 606, *Revenue Recognition*, or ASC 606. Under ASC 606, we recognize revenue following the five steps: (i) identification of the contract(s) with a customer; (ii) identification of the promised goods and services in the contract and determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model once the contract is determined to be within scope of ASC 606 and when we determine that collection of substantially all consideration for goods and services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and whether each promised good or service is distinct and if there are any material rights present. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For each material right identified, if any, the allocated transaction price will be recognized as revenue over the total estimated period of performance upon exercise of the material right, or will be recognized as revenue immediately upon expiration of the replacement right.

As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract as there is not a readily available standalone selling price. Our revenue recognized is related to research services performed for each initial collaboration target whereby revenue was recognized as the underlying services were performed using a costs incurred input method, in which we apply a cost-to-cost method and compare the actual costs incurred to date with the current estimate of total costs to complete, or ETCs, to measure the satisfaction of each performance obligation. We estimate the ETCs utilizing our best knowledge and as there are changes in facts and circumstances, we update our ETCs accordingly for the ongoing and prospective research activities. To the extent the estimates are not appropriate in the circumstances, it could impact the timing of our revenue recognition. We evaluate the measure of progress each reporting period and if estimates related to the measure of progress change, related revenue recognition is adjusted accordingly.

Accrued research and development expenses

In preparing the consolidated financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. This process involves reviewing open contracts, communicating with internal personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We periodically confirm the accuracy of our estimates with our service providers and make adjustments, if necessary. The majority of our service providers invoice in arrears for services performed or when contractual milestones are met. The financial terms of agreements with these service providers are subject to negotiation, vary from contract-to-contract and may result in uneven payment flows. In circumstances where amounts have been paid in excess of costs incurred, we record a prepaid expense.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts incurred.

Stock-based compensation

We account for stock-based compensation under the provisions of ASC Topic 718-10, *Compensation-Stock Compensation*, ASC 718-10, which requires all stock-based payments to employees, non-employees, and directors, including grants of stock options and restricted stock, which we collectively refer to as stock awards, to be recognized in the consolidated statements of operations and comprehensive loss based on their fair values on the date of grant over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. Generally, we issue stock awards with only service-based vesting conditions and record the expense for these awards using the straight-line method. We classify stock-based compensation expense in the same manner in which the awards recipient’s payroll or service provider’s costs are classified.

We estimate the fair value of each option grant using the Black-Scholes option pricing model and we estimate the fair value of each restricted stock grant using the fair value of common stock. The Black-Scholes option pricing model requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, expected dividends, and the fair value of common stock. We estimate the expected stock price volatility based on the historical

volatility of publicly traded peer companies. The expected term of our stock options has been determined utilizing the "simplified" method for awards that qualify as "plain vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. There is no expected dividend yield since we have never paid cash dividends on common stock and do not expect to pay any cash dividends in the foreseeable future.

Determination of fair value of common stock valuations

Prior to our initial public offering in January 2026, there was no public market for our common stock to date. As a result, the estimated fair value of our common stock has been determined by our Board of Directors, or the Board, as of the date of each option grant with input from management, considering our most recently available third-party valuations of common stock, and our Boards' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common stock valuation was prepared using a market approach to estimate our enterprise value and an option pricing method, OPM, to allocate value to the common stock. The OPM treats common stock and convertible preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the convertible preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

Given the absence of a public trading market, our Board, with input from management considered numerous objective and subjective factors to determine the fair value of common stock. The factors included, but were not limited to:

- the prices at which we sold preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- our ability to raise future financings;
- the progress of our research and development efforts, including the status of clinical development for our product candidates;
- the lack of liquidity of our equity as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- the achievement of enterprise milestones, including entering into collaboration and license agreements;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the likelihood of achieving a liquidity event for the holders of our preferred stock and holders of our common stock, such as an initial public offering, or a sale of our company, given prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations were highly complex and subjective and represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

In January 2026, we completed our IPO. As such, the fair value of our common stock will be determined based on the quoted market price of our common stock and it is no longer necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements included elsewhere in this Annual Report.

Emerging Growth Company and Smaller Reporting Company status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, as amended, or JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to use the

extended transition period for complying with new or revised accounting standards and as a result of this election, our consolidated financial statements may not be comparable to companies that comply with public company effective dates. We may take advantage of these exemptions up until the time that we are no longer an “emerging growth company.”

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a “large accelerated filer” under the rules of the SEC, which means, among other things, the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the last business day of our most recently completed second fiscal quarter and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until for so long as either (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

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

As a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act, and pursuant to Item 305 of Regulation S-K, we are not required to provide quantitative and qualitative disclosures about market risk.

Item 8. Financial Statements and Supplementary Data.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the stockholders and the Board of Directors of Aktis Oncology, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Aktis Oncology, Inc. and subsidiary (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows for each of 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 December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ Deloitte & Touche LLP
Boston, Massachusetts
March 30, 2026

We have served as the Company's auditor since 2021.

AKTIS ONCOLOGY, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except shares and par value data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 37,784	$ 37,159
Marketable securities	189,003	260,009
Prepaid expenses and other current assets	3,523	3,685
Total current assets	230,310	300,853
Property and equipment, net	14,595	7,298
Operating lease right-of use assets	12,651	13,573
Restricted cash equivalents	1,149	1,149
Other assets	6,180	3,308
Total assets	$ 264,885	$ 326,181
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,737	$ 1,918
Accrued expenses and other current liabilities	9,522	6,331
Deferred revenue, current portion	18,662	9,277
Operating lease liabilities, current portion	1,315	1,296
Total current liabilities	31,236	18,822
Deferred revenue, net of current portion	36,156	51,039
Operating lease liabilities, net of current portion	10,233	10,714
Total liabilities	77,625	80,575
Commitments and contingencies (Note 13)		
Redeemable convertible preferred stock:		
Series Seed redeemable convertible preferred stock, $0.0001 par value; 5,000,000 shares authorized, issued and outstanding; aggregate liquidation preference of $5,000 as of December 31, 2025	5,000	5,000
Series A redeemable convertible preferred stock, $0.0001 par value; 78,067,500 shares authorized, issued and outstanding; aggregate liquidation preference of $156,135 as of December 31, 2025	145,050	145,050
Series A-1 redeemable convertible preferred stock, $0.0001 par value; 2,500,000 shares authorized, issued and outstanding; aggregate liquidation preference of $10,000 as of December 31, 2025	8,197	8,197
Series B redeemable convertible preferred stock, $0.0001 par value; 43,750,000 shares authorized, issued and outstanding; aggregate liquidation preference of $175,000 as of December 31, 2025	174,654	174,654
Partner redeemable convertible preferred stock, $0.0001 par value; 250,000 shares authorized, issued and outstanding; aggregate liquidation preference of $500 as of December 31, 2025	508	508
Stockholders' deficit:		
Common stock, $0.0001 par value; 156,800,000 and 155,000,000 shares authorized as of December 31, 2025 and 2024, respectively; 915,261 shares and 780,996 shares issued and outstanding as of December 31, 2025 and 2024, respectively	—	—
Additional paid-in capital	10,373	4,906
Accumulated other comprehensive income	42	124
Accumulated deficit	(156,564)	(92,833)
Total stockholders' deficit	(146,149)	(87,803)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 264,885	$ 326,181

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

AKTIS ONCOLOGY, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Year ended December 31,	
	2025	**2024**
Revenue:		
Collaboration revenue	$ 6,497	$ 1,487
Operating expenses:		
Research and development	67,451	40,954
General and administrative (includes $4 and $143 for related parties, respectively)	13,730	12,583
Total operating expenses	81,181	53,537
Loss from operations	(74,684)	(52,050)
Other income (expense):		
Interest income	11,009	8,103
Change in fair value of preferred stock warrant liability	—	(8)
Other expense, net	(56)	(25)
Total other income, net	10,953	8,070
Net loss	$ (63,731)	$ (43,980)
Net loss per share - basic and diluted	$ (78.34)	$ (62.46)
Weighted-average common stock outstanding, basic and diluted	813,524	704,165
Comprehensive loss:		
Net loss	$ (63,731)	$ (43,980)
Other comprehensive (loss) income:		
Net unrealized (loss) gain on marketable securities held	(82)	42
Comprehensive loss	$ (63,813)	$ (43,938)

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

AKTIS ONCOLOGY, INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share amounts)

	Series Seed Redeemable Convertible Preferred Stock		Series A Redeemable Convertible Preferred Stock		Series A-1 Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Partner Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Deficit
Balance as of December 31, 2023	5,000,000	$ 5,000	78,067,500	$ 50	—	$ —	—	$ —	—	$ —	649,738	$ —	$ 2,465	$ 82	$ (48,853)	(46,306)
Vesting of restricted stock	—	—	—	—	—	—	—	—	—	—	33,678	—	2	—	—	2
Issuance of Series A-1 redeemable convertible preferred stock	—	—	—	—	2,500,000	8,197	—	—	—	—	—	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $331	—	—	—	—	—	—	43,750,000	174,654	—	—	—	—	—	—	—	—
Issuance of Partner redeemable convertible preferred stock	—	—	—	—	—	—	—	—	250,000	508	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	2,260	—	—	2,260
Exercise of common stock options	—	—	—	—	—	—	—	—	—	—	97,580	—	179	—	—	179
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	—	42	—	42
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(43,980)	(43,980)
Balance as of December 31, 2024	5,000,000	$ 5,000	78,067,500	$ 50	2,500,000	$ 8,197	43,750,000	$ 4	250,000	$ 508	780,996	$ —	$ 4,906	$ 124	$ (92,833)	$ (87,803)
Stock-based compensation	—	—	—	—	—	—	—	—	—	—	-	—	5,131	—	—	5,131
Exercise of common stock options	—	—	—	—	—	—	—	—	—	—	134,265	—	336	—	—	336
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	—	—	(82)	—	(82)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(63,731)	(63,731)
Balance as of December 31, 2025	5,000,000	$ 5,000	78,067,500	$ 50	2,500,000	$ 8,197	43,750,000	$ 4	250,000	$ 508	915,261	$ —	$ 10,373	$ 42	$ (156,564)	$ (146,149)

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

AKTIS ONCOLOGY, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year ended December 31,	
	2025	**2024**
Cash flows (used in) provided by operating activities		
Net loss	$ (63,731)	$ (43,980)
Adjustments to reconcile net loss to net cash flows (used in) provided by operating activities:		
Depreciation and amortization	2,329	1,575
Stock-based compensation	5,131	2,260
Change in fair value of preferred stock warrant liability	-	8
Net amortization of premiums and accretion of discounts on investments in marketable securities	(4,624)	(4,081)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(872)	(482)
Interest receivable	1,034	(861)
Operating lease right-of-use assets	1,861	1,970
Other assets	(512)	(1,150)
Accounts payable	(44)	360
Accrued expenses and other current liabilities	2,200	2,152
Operating lease liabilities	(1,401)	(1,522)
Deferred revenue	(5,498)	58,513
Net cash (used in) provided by operating activities	(64,127)	14,762
Cash flows provided by (used in) investing activities		
Purchases of marketable securities	(193,868)	(288,396)
Proceeds from maturities of marketable securities	269,416	100,858
Purchases of property and equipment	(9,584)	(2,862)
Net cash provided by (used in) investing activities	65,964	(190,400)
Cash flows (used in) provided by financing activities		
Proceeds from issuance of Series A-1 redeemable convertible preferred stock	—	10,000
Proceeds from issuance of Series B redeemable convertible preferred stock	—	175,000
Payment of issuance costs	—	(346)
Payment of deferred offering costs	(1,548)	(1,549)
Proceeds from exercise of common stock options	336	179
Net cash (used in) provided by financing activities	(1,212)	183,284
Net increase in cash, cash equivalents and restricted cash equivalents	625	7,646
Cash, cash equivalents and restricted cash equivalents at beginning of period	38,308	30,662
Cash, cash equivalents and restricted cash equivalents at end of period	$ 38,933	$ 38,308
Reconciliation of cash, cash equivalents and restricted cash equivalents		
Cash and cash equivalents	$ 37,784	$ 37,159
Long-term restricted cash equivalents	1,149	1,149
Total cash, cash equivalents and restricted cash equivalents	$ 38,933	$ 38,308
Supplemental disclosure of cash flow information:		
Remeasurement of right-of-use asset and lease liability due to lease modification	$ 939	$ 131
Supplemental disclosure of non-cash investing and financing activities:		
Fair value adjustment of Series A-1 redeemable convertible preferred stock	$ —	$ 1,803
Purchases of property and equipment included in accounts payable	$ 477	$ 409
Purchases of property and equipment included in accrued expenses	$ 209	$ 235
Net unrealized (loss) gain on marketable securities	$ (82)	$ 42
Deferred offering costs included in accounts payable	$ -	$ 205
Deferred offering costs included in accrued expenses	$ 1,343	$ 326
Issuance of Partner redeemable convertible preferred stock	$ —	$ 508

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

1. Nature of the business and basis of presentation

Aktis Oncology, Inc. (“Aktis” or the “Company”) was incorporated under the laws of the State of Delaware in August 2020. Its principal office is in Boston, Massachusetts. Aktis Security Corporation, its wholly owned subsidiary, was formed under the laws of the State of Delaware in November 2022. The Company is a clinical-stage oncology company focused on unlocking the breakthrough potential of targeted radiopharmaceuticals for large patient populations not currently addressed by existing technologies. The Company has built a proprietary miniprotein radioconjugate platform that aims to safely confer breakthrough efficacy to a broader range of patient populations.

Risks and uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, the outcome of clinical trials, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technologies, compliance with government regulations, ability to secure additional capital to fund operations, and potential delays associated with the Company’s anticipated and planned trials.

There can be no assurance that the Company will be able to successfully complete the development of, or receive regulatory approval for, any products developed, and if approved, that any products will be commercially viable. Any products resulting from the Company’s current research and development efforts will require significant additional research and development, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel, infrastructure, and extensive compliance reporting capabilities. The Company has not generated any revenue from the sale of any products to date. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Reverse stock split

On January 2, 2026, the Company effected a 1-for-3.8044 reverse stock split of its issued and outstanding common stock, which also resulted in a proportional adjustment to the conversion price for each series of its redeemable convertible preferred stock, and to the exercise prices and number of outstanding stock options. The par value and authorized number of shares of common stock and redeemable convertible preferred stock were not adjusted as a result. All share and per share amounts for all periods presented in the consolidated financial statements and notes thereto have been retroactively adjusted to reflect the effect of the reverse stock split.

Initial public offering

In January 2026, the Company completed its initial public offering ("IPO"), in which the Company sold an aggregate of 17,650,000 shares of its common stock at a public offering price of $18.00 per share and sold an additional 2,647,500 shares of its common stock to the underwriters of the IPO pursuant to the full exercise of their option to purchase additional shares, resulting in aggregate net proceeds of approximately $335.3 million, after deducting underwriter discounts, commissions and other offering expenses. Immediately prior to the closing of the IPO, the Company's outstanding redeemable convertible preferred stock automatically converted into 34,057,218 shares of common stock and 1,872,829 shares of Class A non-voting common stock. Following the closing of the IPO, no shares of redeemable convertible preferred stock were outstanding. In connection with the closing of the IPO, the Company's certificate of incorporation was amended and restated to authorize 480,000,000 shares of common stock, par value $0.0001 per share, 10,000,000 shares of Class A common stock, par value $0.0001 per share and 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share.

Liquidity

In accordance with Accounting Standards Update (“ASU”) 2014-15, *Disclosure of Uncertainties About an Entity’s Ability to Continue as a Going Concern (Subtopic 205-40),* the Company has evaluated whether there are conditions and events that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date the consolidated financial statements are issued. The accompanying consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

From the Company's inception, the Company has primarily funded its operations with proceeds from the issuance of common stock and redeemable convertible preferred stock (see Note 7) and upfront payments upon entering into a Research and Collaboration Agreement (the "Collaboration Agreement") with Eli Lilly and Company ("Eli Lilly") (see Note 12). As of

December 31, 2025, the Company has raised an aggregate of $345.5 million in net proceeds through the sale of redeemable convertible preferred stock and received $60.0 million in upfront payments and $1.0 million from the achievement of the first milestone under the Collaboration Agreement with Eli Lilly. The Company has incurred losses since inception, including net losses of $63.7 million and $44.0 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company had an accumulated deficit of $156.6 million.

The Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within the twelve months after the date that these consolidated financial statements are issued. The Company believes that its existing cash, cash equivalents and marketable securities of $226.8 million as of December 31, 2025, together with the additional proceeds received from the IPO, will be sufficient to allow the Company to fund operations at least twelve months from the date that the financial statements are issued.

Basis of presentation and consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying consolidated financial statements include the accounts of the Company's wholly-owned subsidiary, Aktis Security Corporation. All intercompany balances and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and ASUs of the Financial Accounting Standards Board ("FASB").

2. Summary of significant accounting policies

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 related disclosures of contingent liabilities as of the date of the consolidated financial statements as well as the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies in developing the estimates and assumptions that are used in the preparation of the consolidated financial statements. Management must apply significant judgment in this process. Estimates are based on several factors including the facts and circumstances available at the time the estimates are made, historical experience, risk of loss, general economic conditions and trends, and the assessment of the probable future outcome. Estimates are used in the following areas, among others: revenue recognition, determining the fair value of the Company's common stock; determination of accrued expenses, and research and development expenses, and valuation allowance for deferred tax assets. Additionally, in calculating the right-of-use assets and lease liabilities, estimates and assumptions were used to determine the incremental borrowing rates and expected lease terms. Estimates and assumptions are reviewed periodically and the effects of changes, if any, are reflected in the consolidated statements of operations and comprehensive loss in the period that they are determined.

Segment information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker ("CODM"), in deciding how to allocate resources and assess performance. The Company has one operating segment focused on the research and development of targeted radiopharmaceuticals. The Company's CODM, its President and Chief Executive Officer ("CEO"), manages its operations on a consolidated basis for the purpose of allocating resources. As of December 31, 2025 and 2024, all of the Company's long-lived assets are held in the United States and, for the years ended December 31, 2025 and 2024, all of the Company's revenue is derived from the United States.

Comprehensive Loss

Comprehensive loss includes net loss, as well as other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. Comprehensive loss is composed of net loss and other comprehensive (loss) income. Other comprehensive (loss) income consists of unrealized gains on marketable securities.

Cash and cash equivalents

Cash and cash equivalents consist primarily of demand deposit accounts and deposits in short-term money market funds. Cash equivalents are stated at cost, which approximates fair value. The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents.

Restricted cash equivalents

Restricted cash equivalents are comprised of cash equivalents that are restricted as to withdrawal or use under the terms of certain contractual agreements. Restricted cash equivalents are used as collateral for letters of credit issued by banks related to the

Company's operating leases and laboratory decommissioning commitment and are considered a non-current asset on the consolidated balance sheets.

Marketable securities

Marketable securities are composed of U.S. treasury bills, corporate debt securities, commercial paper and agency bonds with maturities of less than one year from the balance sheet date. The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. The Company classifies all of its marketable securities as available-for-sale pursuant to ASC 320, *Investments–Debt and Equity Securities.* The Company records available-for-sale securities at fair value with unrealized gains and losses included in accumulated other comprehensive income. The cost of marketable securities is adjusted for amortization of premiums and accretion of discounts until maturity. Such amortization and accretion, along with any interest income received, are included in interest income, which is a component of other income (expense). Realized gains and losses are included in other expense, net. The Company reviews any investment when its fair value is less than its amortized cost and when evidence indicates that the investment's carrying amount is not recoverable within a reasonable period. The Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss exists and if the present value of cash flows expected to be collected is less than the amortized cost basis, an allowance for credit losses is recorded on its consolidated balance sheets, limited by the amount that the fair value is less than the amortized cost basis. Any impairment that is not related to a credit loss is recognized in other comprehensive (loss) income.

Changes in the allowance for credit losses are recorded as a provision for (or reversal of) credit loss. Losses are charged against the allowance for credit losses when the Company believes the uncollectibility of an investment is confirmed or when the Company intends to sell, or more likely than not will be required to sell the security before recovery of its amortized cost basis.

The Company evaluates marketable securities for other-than-temporary impairment at the balance sheet dates. Declines in fair value, if any, determined to be other than temporary are also included in other income (expense).

Concentration of credit risk

Financial instruments that subject the Company to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company places its cash, cash equivalents and marketable securities in financial institutions that management believes to be of high credit quality, and accordingly, the Company believes such funds are subject to minimal credit risk. The Company maintains its cash in bank deposit accounts that at times exceed federally insured limits. The Company has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Property and equipment

Property and equipment are recorded at cost, less accumulated depreciation and amortization. Depreciation is recorded using the straight-line method over the estimated useful lives of the respective assets. Expenditures for maintenance and repairs are charged to expense while the costs of significant improvements are capitalized. Upon retirement or sale, the costs of the assets disposed of and the related accumulated depreciation or amortization is eliminated from the consolidated balance sheets and any related gains or losses are reflected in the consolidated statements of operations and comprehensive loss. The range of useful lives of property and equipment is as follows:

Description	Useful life
Computer equipment	3 Years
Computer software	3 Years
Office equipment & furniture	5 Years
Lab equipment	5 Years
Leasehold improvements	The shorter of the life of the leasehold improvement or the remaining term of the lease

Impairment of long-lived assets

Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to their undiscounted expected future cash flows. If the undiscounted cash flows are insufficient to recover the carrying value, the assets are recorded at the lesser of the carrying value or fair value. To date, the Company has not recorded any impairment losses on long-lived assets.

Patent-related costs

Patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the accompanying consolidated statements of operations and comprehensive loss.

Fair value measurements

Certain assets and liabilities are carried at fair value in accordance with GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Valuation techniques used to measure fair value require the Company to maximize the use of observable inputs and minimize the use of unobservable inputs. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

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

The Company's financial instruments consist of cash equivalents, restricted cash equivalents, marketable securities, other current assets, accounts payable, and accrued expenses and other current liabilities. The Company's marketable securities are carried at fair value, determined according to Level 1 and Level 2 inputs to the fair value hierarchy described above. Preferred stock warrant liabilities are measured at fair value on a recurring basis utilizing a hybrid approach (see Note 3). The remaining financial instruments are stated at their respective carrying amounts, which approximate fair value due to the short-term nature of these assets and liabilities.

Research and development costs

The Company expenses research and development costs as incurred. Research and development expenses consist principally of personnel costs including employee payroll and stock-based compensation, consumable laboratory materials and supplies, contracted external laboratory services and facility costs including allocated overhead such as rent, depreciation, utilities and maintenance expense, license and milestones fees, and other related costs.

Accrued research and development costs

The Company has entered into various research and development contracts. The payments under these contracts are recorded as research and development expenses as incurred. The Company records accrued expenses for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of its research and development studies, including the phase or completion of events, invoices received and contracted costs. Judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Asset acquisitions and acquired in-process research and development expense

The Company accounts for acquisitions of assets or a group of assets that do not meet the definition of a business as asset acquisitions based on the cost to acquire the asset or group of assets, which include certain transaction costs. In an asset acquisition, the cost to acquire is allocated to the identifiable assets acquired and liabilities assumed based on their relative fair values as of the acquisition date. No goodwill is recorded in an asset acquisition. Assets that are acquired in an asset acquisition for use in research and development activities that have an alternative future use are capitalized as in process research and development ("IPR&D") while those acquired that have no alternative future use as of the acquisition date are recognized as research and development expense as of the acquisition date. The Company will recognize additional research and development expenses in the future if and when the Company becomes obligated to make contingent milestone payments under the terms of the agreements by which it acquired the IPR&D assets. Contingent consideration in the form of milestone payments related to IPR&D with no alternative future use is charged to expense when the related milestone is achieved and becomes payable.

Stock-based compensation expense

The Company accounts for stock-based compensation under the provisions of ASC 718-10, *Compensation—Stock Compensation* ("ASC 718-10"), which requires all stock-based payments (such as grants of stock options and restricted stock) to employees, non-employees and directors, to be recognized in the consolidated statements of operations and comprehensive loss based on their fair values on the date of grant over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. Generally, the Company issues stock option awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company classifies stock-based compensation expenses in the same manner in which the awards recipient's payroll or service provider's costs are classified.

The fair value of each restricted stock award is estimated on the date of grant based on the fair value of the Company's common stock on that same date.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model ("Black-Scholes"), which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends. The Company estimates its expected stock price volatility based on the historical volatility of publicly traded peer companies. The Company uses the simplified method as prescribed by the Securities and Exchange Commission's Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for stock options granted to employees as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. There is no expected dividend yield since the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Prior to the Company's IPO, the fair value of the Company's common stock on the date of grant was determined by the Company's Board of Directors (the "Board"), taking into consideration its most recently available third-party valuations of common stock as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the grant date.

Redeemable convertible preferred stock

The Company has classified its redeemable convertible preferred stock as temporary equity in the accompanying consolidated balance sheets due to redemption provisions related to a change in control event that are outside of the control of the Company (see Note 7). The Company did not accrete the carrying values of the redeemable convertible preferred stock to the redemption values since a change in control event was not considered probable at period end. Subsequent adjustments of the carrying values to the redemption values will be made only when it becomes probable that such a change in control event will occur.

Derivative instruments

The Company enters into, from time to time, financial instrument agreements in which a derivative instrument is "embedded". Upon issuing the financial instrument, the Company assesses whether the economic characteristics of the embedded derivative instrument are clearly and closely related to the economic characteristics of the host contract and whether a separate, instrument with the same terms as the embedded derivative instrument would meet the definition of a derivative instrument.

When it is determined that (1) the embedded derivative instrument possesses economic characteristics that are not clearly and closely related to the economic characteristics of the host contract and (2) a separate instrument with the same terms would qualify as a derivative instrument, the embedded derivative instrument is separated from the host contract and carried at fair value with any changes in fair value recorded in current period earnings.

Income taxes

The Company accounts for income taxes using the asset and liability approach. Deferred tax assets and liabilities represent future tax consequences of temporary differences between the consolidated financial statement carrying amounts and the tax basis of assets and liabilities and for loss carryforwards using enacted tax rates expected to be in effect in the years in which the differences reverse. A valuation allowance is established to reduce deferred tax assets to the amounts expected to be realized. The Company also recognizes a tax benefit from uncertain tax positions only if it is "more likely than not" that the position is sustainable based on its technical merits. The Company accounts for interest and penalties related to uncertain tax positions as part of its provision for income taxes. To date, the Company has not incurred interest and penalties related to uncertain tax positions.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues loss contingencies when losses become probable and are reasonably estimable. If the reasonable estimate of

the loss is a range and no amount within the range is a better estimate, the minimum amount of the range is recorded as a liability on the Company's consolidated balance sheets. The Company does not accrue contingent losses that, in its judgment, are considered to be reasonably possible, but not probable; however, it discloses the range of reasonably possible losses. There were no loss contingencies recorded in the Company's consolidated financial statements for the years ended December 31, 2025 and 2024.

Leases

The Company accounts for its leases in accordance with ASU No. 2016-02, *Leases* (Topic 842) ("ASU 2016-02" or "ASC 842"). At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease. A contract is or contains a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. At the lease commencement date, when control of the underlying asset is transferred from the lessor to the Company, the Company classifies a lease as either an operating or finance lease and recognizes a right-of-use ("ROU") asset and a current and non-current lease liability as applicable, in the consolidated balance sheet if the lease has a term greater than one year. As permitted under ASC 842, the Company has made an accounting policy election, for all classes of underlying assets, to not recognize ROU assets and lease liabilities for leases having a term of twelve months or less. When it determines the lease term, the Company considers the committed lease term and any options available in the lease agreement. The Company's lease terms may include options to extend the lease, or the option to purchase the asset, only when it is reasonably certain that the Company will exercise that option.

The Company enters into contracts that contain both lease and non-lease components. Non-lease components include costs that do not provide a right to use a leased asset but instead provide a service, such as maintenance costs. In accordance with ASC 842, the Company has elected to combine the lease and non-lease components together as a single lease component for all existing classes of underlying assets. Lease cost for operating leases is recognized on a straight-line basis over the lease term as an operating expense on the consolidated statements of operations and comprehensive loss. For finance leases, amortization expense and interest expense are recognized separately in the consolidated statements of operations, and comprehensive loss with amortization expense recognized on a straight-line basis and interest expense recognized using the effective interest method. Variable costs associated with the lease, such as maintenance and utilities, are not included in the measurement of right-to-use assets and lease liabilities but rather are expensed when the events determining the amount of variable consideration to be paid have occurred.

Net loss per common share

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities, which includes warrants, outstanding stock options, and redeemable convertible preferred stock. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of diluted securities and dividing the resulting amount by the weighted-average number of common shares outstanding for the period, including potential dilutive common shares. For the purpose of this calculation, warrants, outstanding stock options, and redeemable convertible preferred stock are considered potential dilutive common shares.

The Company's redeemable convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require those holders to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is antidilutive.

Emerging growth company status

The Company is an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act") and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not EGCs. The Company may take advantage of these exemptions until it is no longer an EGC under Section 107 of the JOBS Act and has the ability to use the extended transition period for complying with new or revised accounting standards. As a result of this election, the Company's consolidated financial statements may not be comparable to companies that comply with public company FASB standards' effective dates. The Company intends to take advantage of the reduced reporting requirements and exemptions up until the last day of the fiscal year following the fifth anniversary of an offering or such earlier time that it is no longer an EGC.

Deferred offering costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are incremental and directly associated with in-process equity financings as deferred offering costs until such financing is consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds generated as a result of the offering within additional paid in capital. In the event that the equity financing is abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss. The Company recorded deferred offering costs related to the IPO of $4.5 million and $2.1 million within other assets as of December 31, 2025 and 2024.

Collaborative arrangements

The Company enters into license and collaboration arrangements with third parties, under which the Company licenses or may license rights to certain of the Company's product candidates and performs research and development services in connection with such arrangements. The terms of these arrangements typically include payment of one or more of the following: non-refundable, upfront fees; reimbursement of research and development costs; development, clinical, regulatory and commercial sales milestone payments, and royalties on net sales of licensed products.

At contract inception, the Company analyzes its license and collaboration arrangements to assess whether such arrangements are within the scope of ASC Topic 808, *Collaborative Arrangements* ("ASC 808"). This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For arrangements within the scope of ASC 808 that contain multiple units of account, the Company first determines which units of the arrangements are deemed to be within the scope of ASC 808 and which units of the arrangements are more reflective of a vendor-customer relationship and, therefore, within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606").

Contracts are considered to be collaborative arrangements when they satisfy the following criteria defined in ASC 808: (i) the parties to the contract must actively participate in the joint operating activity and (ii) the joint operating activity must expose the parties to the possibility of significant risks and rewards, based on whether or not the activity is successful. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, either by analogy to authoritative accounting literature or by applying a reasonable and rational policy election.

Revenue recognition

Revenue from contracts with customers

The Company recognizes revenue in accordance with ASC 606. ASC 606 provides a five-step framework whereby revenue is recognized when control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the Company expects to be entitled. To determine the appropriate amount of revenue to be recognized on a contract, the Company performs the following five steps: (i) identification of the contract(s) with a customer; (ii) identification of the promised goods and services in the contract and determination of whether the promised goods or services are performance obligations including whether they are distinct; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model once the contract is determined to be within scope of ASC 606 and when the Company determines that collection of substantially all consideration for goods and services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

The promised goods or services in the Company's contracts typically consist of a grant of a license to the Company's intellectual property and provision of research and development services. The Company provides options to additional items in such contracts, which are accounted for as separate contracts when the customer elects to exercise such options, unless the option provides a material right to the customer. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer and are considered distinct when (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, the Company considers factors such as the stage of development of the underlying intellectual property, the capabilities of the customer to develop the intellectual property on its own or whether the required expertise is readily available and whether the goods or services are integral or dependent to other goods or services in the contract.

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, including research, development, clinical, regulatory and sales-based milestone payments, 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 management's judgment, it is probable that a significant future reversal of cumulative revenue recognized 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 relates to that 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 Company satisfies performance obligations either over time or at a point in time. Revenue is recognized over time if either (i) the customer simultaneously receives and consumes the benefits provided by the entity's performance, (ii) the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced, or (iii) 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.

The Company's contracts often include development and regulatory milestone payments, which are variable considerations, that are assessed under the most likely amount method and constrained until it is probable that a significant revenue reversal would not occur. Due to the uncertainty of development and regulatory based milestones that are not within the control of the Company, payment becomes probable upon achievement. At the end of each reporting period, the Company re-evaluates the probability of achievement of such development and regulatory milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue in the period of adjustment.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license granted is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation related to the royalty, has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of the Company's license and collaboration agreements.

Deferred revenue expected to be recognized within the next twelve months is classified as a current liability.

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 an account or other receivable. A contract asset represents the Company's right to consideration in exchange for goods or services that the Company has transferred to a customer. The contract liabilities, or deferred revenue, relate to contracts where the Company has received payment, but it has not yet satisfied or fully satisfied the related performance obligations. Upfront payments and fees are recorded as deferred revenue upon receipt and may require deferral of revenue recognition to a future period until the Company satisfies its obligations under the contracts. Upfront payment contract liabilities resulting from the Company's license and collaboration agreements do not include a financing component as the payment is not financing the transfer of goods or services, and the technology underlying the licenses granted reflects research and development expenses already incurred by the Company.

Recently adopted accounting pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvement to Income Tax Disclosures*, ("ASU 2023-09"). ASU 2023-09 provides more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. For public and private companies, the amendments are effective for annual periods beginning after December 15, 2024, and 2025, respectively, with retrospective application permitted. The Company adopted the standard effective January 1, 2025 on a prospective basis. See Note 10, Income taxes, for further disclosure.

Recent accounting pronouncements not yet adopted

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures*, ("ASU 2024-03"). ASU 2024-3 requires disclosure of additional information about specific expense categories in the notes to the financial statements on an interim and annual basis. The standard is effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027, with prospective or retrospective application and early adoption permitted. The Company is currently evaluating the disclosure requirements related to this new standard.

3. Fair value measurements

The following table sets forth by level, within the fair value hierarchy, the financial assets and liabilities carried at fair value on a recurring basis (in thousands):

	Fair value measurements as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 37,284	$ —	$ —	$ 37,284
Marketable securities:				
Commercial paper	—	55,292	—	55,292
Treasury bills	87,973	-	—	87,973
Corporate debt securities	—	18,529	—	18,529
Agency bonds	—	27,209	—	27,209
Total marketable securities	87,973	101,030	—	189,003
Restricted cash equivalents	1,149	—	—	1,149
Total financial assets	$ 126,406	$ 101,030	$ —	$ 227,436

	Fair value measurements as of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 36,659	$ —	$ —	$ 36,659
Marketable securities:				
Commercial paper	—	93,765	—	93,765
Treasury bills	116,311	—	—	116,311
Corporate debt securities	—	15,025	—	15,025
Agency bonds	—	34,908	—	34,908
Total marketable securities	116,311	143,698	—	260,009
Restricted cash equivalents	1,149	—	—	1,149
Total financial assets	$ 154,119	$ 143,698	$ —	$ 297,817

During the years ended December 31, 2025 and 2024, there were no transfers or reclassifications between fair value measurement levels of financial assets. The carrying values of prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate their fair values due to the short-term nature of these assets and liabilities. The Company had no other financial liabilities for the periods presented above.

Valuation of marketable securities

The Company classifies its treasury bills as Level 1 assets under the fair value hierarchy, as these securities have been valued using quoted market prices for identical assets in active markets without any valuation adjustment. The Company classifies its commercial paper, corporate debt securities, and agency bonds as Level 2 assets under the fair value hierarchy, as these assets have been valued using quoted prices in active markets for similar securities.

4. Marketable securities

As of December 31, 2025 and 2024, the Company's security portfolio consisted of 56 securities and 49 securities, respectively, related to marketable securities in debt securities available-for-sale, of which there were 10 securities in unrealized loss positions as of December 31, 2025 and 2024. There were no securities in an unrealized loss position for greater than 12 months as of December 31, 2025 or 2024. The Company does not intend to sell the marketable securities prior to the value of the securities being recovered and it is not more likely than not that the Company will be required to sell the marketable securities before recovery of their amortized cost basis. The Company did not record an allowance for credit losses as of December 31, 2025 or 2024. Accrued

interest receivable relating to the Company's available-for-sale securities is presented within prepaid expenses and other current assets in the accompanying consolidated balance sheets, and amounted to $1.1 million as of December 31, 2025 and 2024.

Marketable securities, which are classified as available-for-sale, consisted of the following (in thousands):

	December 31, 2025			
	Amortized Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Commercial paper	$ 55,300	$ 10	$ (18)	$ 55,292
Treasury bills	87,924	49	-	87,973
Corporate debt securities	18,533	5	(9)	18,529
Agency bonds	27,204	10	(5)	27,209
Total marketable securities	$ 188,961	$ 74	$ (32)	$ 189,003

	December 31, 2024			
	Amortized Cost Basis	Unrealized Gain	Unrealized Loss	Fair Value
Commercial paper	$ 93,765	$ 39	$ (39)	$ 93,765
Treasury bills	116,199	112	-	116,311
Corporate debt securities	15,025	11	(11)	15,025
Agency bonds	34,896	12	-	34,908
Total marketable securities	$ 259,885	$ 174	$ (50)	$ 260,009

5. Property and equipment, net

Property and equipment consisted of the following (in thousands):

	December 31,	
	2025	2024
Laboratory equipment	$ 12,149	$ 8,274
Computer equipment	81	66
Computer software	216	216
Office equipment & furniture	520	472
Leasehold improvements	167	167
Assets under construction	7,007	1,332
Total property and equipment	20,140	10,527
Less: Accumulated depreciation and amortization	(5,545)	(3,229)
Property and equipment, net	$ 14,595	$ 7,298

The Company recorded depreciation expense of $2.3 million and $1.6 million for the years ended December 31, 2025 and 2024, respectively.

6. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2025	2024
Accrued compensation and benefit costs	$ 4,564	$ 3,084
Accrued research and development costs	2,958	2,307
Accrued professional costs	192	89
Other accrued expenses	1,808	851
Total accrued expenses and other current liabilities	$ 9,522	$ 6,331

7. Redeemable convertible preferred stock

In August 2020, the Company issued 5,000,000 shares of Series Seed redeemable convertible preferred stock (the "Series Seed Preferred Stock") for total net proceeds of $5.0 million pursuant to the Series Seed Preferred Stock Purchase Agreement (the “Series Seed Agreement”) between the Company and certain investors.

In February 2021, the Company entered into the first Series A Preferred Stock Purchase Agreement (the “First Series A Agreement”) which provided for the purchase of Series A redeemable convertible preferred stock (the "Series A Preferred Stock"). The Company in the initial closing of Series A Preferred Stock issued 18,000,000 shares for net proceeds of approximately $35.9 million. The First Series A Agreement granted investors the right to purchase an additional 18,000,000 shares of Series A Preferred Stock at a price of $2.00 per share (the "Preferred Stock Tranche Right") upon the earlier of (i) satisfaction of a milestone event, which is when the Company identifies at least one molecule that meets the criteria for lead nomination or (ii) a waiver of such condition by holders of sixty five percent of the Preferred Shares then issued and outstanding (the “Milestone Closing”) prior to February 26, 2023.

The Company determined that the Preferred Stock Tranche Right was a freestanding instrument as it was both legally detachable and separately exercisable. The initial fair value of the Preferred Stock Tranche Right was determined to be $10.8 million and was extinguished in January 2022 upon the Milestone Closing, which resulted in 18,000,000 shares of Series A Preferred Stock being issued to the investors for net proceeds of approximately $35.9 million.

In August 2022, the Company entered into a second Series A Preferred Stock Purchase Agreement (the "Second Series A Agreement") and issued an additional 42,067,500 shares of Series A Preferred Stock for net proceeds of approximately $84.0 million.

In May 2024, the Preferred Stock Warrants were exercised for nominal consideration and the Company issued 250,000 shares of Partner Preferred Stock.

In May 2024, the Company entered into the Series A-1 Preferred Stock Purchase Agreement (the "Series A-1 Agreement") in connection with the Collaboration Agreement that the Company entered into with Eli Lilly (see Note 12). Under the Series A-1 Agreement, the Company issued 2,500,000 shares of Series A-1 redeemable convertible preferred stock (the "Series A-1 Preferred Stock") at $4.00 per share for gross proceeds of $10.0 million. The Company determined the fair value of the shares sold under this transaction to be $8.2 million with the excess consideration received being included in the transaction price of the Collaboration Agreement.

In September 2024, the Company entered into the Series B Preferred Stock Purchase Agreement (the "Series B Agreement"), which resulted in the issuance of 43,750,000 shares of Series B redeemable convertible preferred stock ("Series B Preferred Stock", together with the Series Seed Preferred Stock, Series A Preferred Stock, Series A-1 Preferred Stock and Partner Preferred Stock, the "Preferred Stock") at $4.00 per share for net proceeds of approximately $174.7 million.

Preferred Stock consisted of the following (in thousands, except share amounts):

	December 31, 2025				
	Authorized	Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series Seed Preferred Stock	5,000,000	5,000,000	$ 5,000	$ 5,000	1,314,262
Series A Preferred Stock	78,067,500	78,067,500	145,050	156,135	20,520,285
Series A-1 Preferred Stock	2,500,000	2,500,000	8,197	10,000	657,133
Series B Preferred Stock	43,750,000	43,750,000	174,654	175,000	11,499,825
Partner Preferred Stock	250,000	250,000	508	500	65,713
Total Preferred Stock	129,567,500	129,567,500	$ 333,409	$ 346,635	34,057,218

	December 31, 2024				
	Authorized	Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series Seed Preferred Stock	5,000,000	5,000,000	$ 5,000	$ 5,000	1,314,262
Series A Preferred Stock	78,067,500	78,067,500	145,050	156,135	20,520,285
Series A-1 Preferred Stock	2,500,000	2,500,000	8,197	10,000	657,133
Series B Preferred Stock	43,750,000	43,750,000	174,654	175,000	11,499,825
Partner Preferred Stock	250,000	250,000	508	500	65,713
Total Preferred Stock	129,567,500	129,567,500	$ 333,409	$ 346,635	34,057,218

As of December 31, 2025, the holders of the Preferred Stock have the following rights and preferences:

Voting

Holders of the Preferred Stock are entitled to one vote with the common stockholders on an as-converted basis at all meetings of stockholders.

Dividends

Holders of outstanding shares of Preferred Stock are entitled to non-cumulative dividends at a rate of 8% of the Original Issue Price per share, per annum, payable if, and when declared by the Board of Directors (the "Board"). The Original Issue Price is $1.00 per share for Series Seed Preferred Stock, $2.00 per share for Partner Preferred Stock and Series A Preferred Stock, and $4.00 per share for Series A-1 Preferred Stock and Series B Preferred Stock subject to appropriate adjustment in the event of any stock dividend, stock split, or other similar recapitalization with respect to the Preferred Stock. Holders of the Preferred Stock participate in any dividends payable to common shareholders on an as-converted basis.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the corporation, or upon the occurrence of a Deemed Liquidation Event (defined below), the holders of shares of the Series A Preferred Stock, Series A-1 Preferred Stock and Series B Preferred Stock are entitled to preferential payments, in an amount calculated as the greater of (i) the applicable Original Issue Price, plus dividends declared but unpaid and (ii) the amount payable with respect to such share as if it was converted to common stock immediately prior to settlement (the “Preferred Stock Liquidation Amount”). After payments due to holders of Series A Preferred Stock, Series A-1 Preferred Stock and Series B Preferred Stock, the holders of Series Seed Preferred Stock will be paid out the Preferred Stock Liquidation Amount. Subsequent to the payment to the holders of Series Seed Preferred Stock, the holders of the Partner Preferred Stock will be paid out the Preferred Stock Liquidation Amount.

A "Deemed Liquidation Event" is defined as (i) a merger or consolidation, or (ii) (1) the sale, lease transfer, exclusive license or other disposition in a single transaction or series of related transactions of all assets of the Company, or (2) the sale or disposition of one or more subsidiaries of the Company if substantially all of the assets of the Company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries,

Conversion

Each share of the Preferred Stock may convert, at any time, into shares of common stock at the Conversion Price. The Conversion Price is equal to the original issue price, subject to adjustments, resulting in an initial conversion ratio of 1:1. The Preferred Stock will automatically convert into common stock at the then effective conversion price upon (a) a qualified IPO pursuant to the Company’s amended Articles of Incorporation or (b) upon the written consent of the holders of the Preferred Stock.

All shares of Preferred Stock automatically converted into shares of common stock on a 1-to-3.8044 basis in connection with the Company's IPO in January 2026 (see Note 1).

Redemption

The Preferred Stock does not contain any mandatory redemption features. In accordance with ASC 480, preferred stock issued with redemption provisions that are outside of the control of the Company, including a deemed liquidation event, is required to be presented outside of stockholders’ deficit on the face of the consolidated balance sheets. The Company’s Preferred Stock contains redemption provisions that require it to be presented outside of stockholders’ deficit.

8. Stockholders' deficit

Common stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders provided, however, that, except as otherwise required by law, holders of common stock are not be entitled to vote on any amendment to the Company's Certificate of Incorporation that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to the Certificate of Incorporation or pursuant to the General Corporation Law. There is no cumulative voting. Common stockholders are entitled to receive dividends, as may be declared by the Company's Board, if any, subject to the preferential dividend rights of the Preferred Stock. During the year ended December 31, 2025, the Company increased the total number of common shares authorized from 155,000,000 shares to 156,800,000 shares. Through December 31, 2025, no dividends have been declared or paid.

The Company's common stock available for future issuance is summarized below:

	December 31,	
	2025	**2024**
Common stock authorized	156,800,000	155,000,000
Common stock outstanding	915,261	780,996
Common stock authorized and reserved for future issuances:		
Series Seed Preferred Stock	1,314,262	1,314,262
Series A Preferred Stock	20,520,285	20,520,285
Series A-1 Preferred Stock	657,133	657,133
Series B Preferred Stock	11,499,825	11,499,825
Partner Preferred Stock	65,713	65,713
Stock options outstanding	5,899,875	5,283,340
Common stock reserved for future grant under the 2020 Equity Incentive Plan	285,723	563,391
Total common stock authorized and reserved for future issuance	40,242,816	39,903,949
Unreserved common stock available for future issuance	115,641,923	114,315,055

9. Equity-based compensation

Stock options

On August 27, 2020, the Board adopted and approved the 2020 Equity Incentive Plan (the "2020 Plan") under which stock options, restricted stock, and other awards as determined by the Board could be granted to employees, non-employees and directors of the Company. Each award granted may be evidenced by an award agreement between the Company and the grantee. Under the 2020 Plan, both incentive stock options ("ISOs") and non-qualified stock options ("NSOs") could be granted. ISOs may be granted only to the Company's employees. The 2020 Plan is administered by the Board. The terms of the awards issued under the 2020 Plan, including vesting requirements, are determined by the Board or compensation committee of the Board. As of December 31, 2025, there were 285,723 shares of common stock available for future grant under the 2020 Plan.

The exercise price of stock options granted under the 2020 Plan generally may not be less than the market price of the common stock at the time of grant. Stock options generally vest over four years with a 25% vesting on the one-year anniversary of the grant date and the remainder vesting in equal monthly installments thereafter and have a maximum term of 10 years. The stock options granted contain only service conditions as the grantees are only required to provide services to the Company over the requisite service period to continue to vest in the awards.

Compensation cost is recognized on a straight-line basis over the requisite service period. As of December 31, 2025, the total unrecognized compensation related to unvested stock option awards was $15.5 million which the Company expects to recognize over a weighted-average period of approximately 2.73 years.

The following table summarizes the stock option activity under the 2020 Plan during the year ended December 31, 2025:

	Number of Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of January 1, 2025	5,283,340	$ 5.07	8.23	$ 29,512
Granted	784,343	10.59	—	—
Exercised	(134,265)	2.50	—	1,163
Cancelled	(33,543)	3.72	—	—
Outstanding as of December 31, 2025	5,899,875	$ 5.87	7.56	$ 32,946
Options vested and exercisable as of December 31, 2025	3,304,413	$ 3.87	6.59	$ 25,051
Options unvested and expected to vest as of December 31, 2025	2,595,462	$ 8.41	8.80	$ 7,895

The weighted-average grant date fair value per share of stock options granted during the years ended December 31, 2025 and 2024 was $8.14 and $5.95, respectively. The total intrinsic value of stock options exercised during the years ended December 31, 2025 and 2024 was $1.2 million and $0.4 million, respectively.

The following table presents, on a weighted-average basis, the assumptions used in the Black Scholes option-pricing model to determine the grant-date fair value of the stock options granted during the years ended:

	December 31,	
	2025	2024
Expected term (in years)	6.01	6.04
Risk-free interest rate	3.93%	4.12%
Expected volatility	91.55%	82.83%
Dividend yield	—	—

Stock-based compensation expense

The following table summarizes stock-based compensation expense included in operating expenses (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 2,667	$ 1,067
General and administrative	2,464	1,193
Total	$ 5,131	$ 2,260

10. Income taxes

The Company's loss before income taxes and net loss for the years ended December 31, 2025 and December 31, 2024 was from its U.S. domestic operations. The Company had no current or deferred federal or state income tax expense due to operating losses incurred for the years ended December 31, 2025 and 2024 and the full valuation allowance recorded on net deferred tax assets.

The difference between the Company's effective income tax rate and the U.S. federal statutory rate of 21% was primarily driven by the change in the valuation allowance. A reconciliation of the federal statutory income tax rate to the Company's effective tax rate after the adoption of ASU 2023-09 is as follows:

	Year Ended December 31,	
	2025	
At statutory rate	$ (13,383)	21.0%
State income taxes, net of federal effect	—	0.0%
Change in valuation allowance	15,754	(24.7%)
Nontaxable or nondeductible items	413	(0.7%)
Changes in tax laws or rates	—	0.0%
Federal research and development credits	(2,784)	4.4%
Cross-border tax laws	—	0.0%
Worldwide changes in unrecognized tax benefits	—	0.0%
Other	0	0.0%
Effective income tax rate	$ —	(0.0%)

A reconciliation of the U.S. federal statutory income tax rate to the Company’s effective income tax rate prior to the adoption of ASU 2023-09 is as follows:

	Year Ended December 31,
	2024
U.S. federal statutory rate	21.0%
State taxes, net of federal benefit	4.9%
Other	(0.5%)
Valuation allowance	(29.3%)
Tax credits	3.9%
Effective income tax rate	0.0%

The components of the Company’s deferred taxes are as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 12,866	$ 9,614
Federal and state research and development credits	7,768	4,605
Lease liabilities	4,083	3,754
Start up and amortized costs	80	78
Accruals and other	2,990	1,688
Deferred revenue	15,687	—
Section 174–Research and development expenses capitalized	16,368	16,020
Gross deferred tax assets	59,842	35,759
Valuation allowance	(54,720)	(30,710)
Net deferred tax assets	$ 5,122	$ 5,049
Deferred tax liabilities:		
Property and equipment	$ (1,451)	$ (1,543)
Operating lease right-of-use asset	(3,671)	(3,506)
Total deferred tax liabilities	$ (5,122)	$ (5,049)
Net deferred tax assets (liability)	$ —	$ —

The Company has evaluated the positive and negative evidence bearing upon its ability to realize its deferred tax assets, which are comprised primarily of net operating loss carryforwards ("NOLs"), the capitalization of research and experimental expenditures, tax credits, and deferred revenue. Management has considered the Company's history of cumulative net losses in the United States, estimated future taxable income and prudent and feasible tax planning strategies and has concluded that it is more likely than not that the Company will not realize the benefits of its U.S. federal and state deferred tax assets and as such the Company has provided a valuation allowance for the full amount of the net deferred tax assets.

As of December 31, 2025, the Company had NOLs for federal and state income tax purposes of $45.8 million and $40.8 million, respectively. As of December 31, 2024, the Company had NOLs for federal and state income tax purposes of $37.7 million and $21.3 million, respectively. The entire federal NOL balance of $45.8 million was generated after 2017 and will be carried forward indefinitely and could be used to offset up to 80% of taxable income of each future tax year. State NOLs of $40.8 million will be carried forward and begin to expire in 2041. As of December 31, 2025 and 2024, the Company has federal tax credits of $6.9 million and $4.1 million, respectively, and state research and development credits of $0.9 million and $0.5 million which begin to expire in 2041 and 2037, respectively.

The valuation allowance increased in 2025 by $24.0 million due to the increase in net deferred tax assets having a full valuation allowance (primarily due to the increase in deferred revenue, section 174-research and development expenses capitalized, NOL carryforwards and research and development credits). The valuation allowance increased in 2024 by $13.5 million due to the increase in net deferred tax assets having a full valuation allowance (primarily due to the increase in section 174-research and development expenses capitalized, the NOL carryforwards and research and development credits).

Future realization of the tax benefits of existing temporary differences related to NOLs and federal and state research and development credits, ultimately depends on the existence of sufficient taxable income within the carryforward period. As of December 31, 2025 and 2024, the Company performed an evaluation to determine whether a valuation allowance was needed. The Company considered all available evidence, both positive and negative, which included the results of operations for the current and preceding years. The Company determined that it was not possible to reasonably quantify future taxable income and determined that it is more likely than not that all the deferred tax assets will not be realized. Accordingly, the Company maintained a full valuation allowance against its net deferred tax assets as of December 31, 2025 and 2024.

As required under ASU 2023-09, the Company has included only the portion of the valuation allowance related to federal deferred tax assets in the "change in valuation allowance" line of the rate reconciliation. The following table presents a reconciliation of the total change in the valuation allowance (in thousands):

	December 31, 2025
Beginning balance	$ 30,711
Change charged to income tax expense	24,027
Changes charged to other comprehensive income	(18)
Ending balance	$ 54,720

Under Internal Revenue Code Section 382, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result, the Company is not able to estimate the effect of the change in control, if any, on the Company's ability to utilize NOL and federal and state research and development credits carryforwards in the future. At this time, the Company has not completed an Internal Revenue Code 382 analysis. However, at such time that the Company does conduct such analysis, the Company may conclude that some or all of the Company's tax attributes are limited.

The Tax Cuts and Jobs Act resulted in significant changes to the treatment of research and developmental expenditures under Section 174 of the Internal Revenue Code. For tax years beginning after December 31, 2021, taxpayers are required to capitalize and amortize all research and developmental expenditures that are paid or incurred in connection with their trade or business. Per the One Big Beautiful Bill Act, effective July 4, 2025, taxpayers are still required to capitalize foreign research and development expenditures over 15 years, but now have the opportunity to deduct domestic research and development expenditures under IRC 174A. The Company has elected to continue to amortize prior year domestic capitalized costs until the amortization of such costs is complete. As of December 31, 2025 and 2024, the Company capitalized $9.5 million and $37.8 million, respectively, of research and developmental expenditures.

As of December 31, 2025 and 2024, the Company had no uncertain tax positions relevant to the jurisdictions where it is required to file income tax returns requiring recognition in the consolidated financial statements. As of December 31, 2025 and 2024, the Company had no accrued interest or penalties related to uncertain tax positions.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending

tax examinations. The Company's tax years are all still open since inception and will remain open to examination by the major taxing jurisdictions to which the Company is subject, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service or other authorities if they have or will be used in a future period.

11. License agreements

Blaze Agreement

On July 22, 2021, the Company entered into the Blaze Agreement, as amended on March 3, 2022, May 20, 2022 and December 19, 2022, pursuant to which the Company and Blaze will grant to each other certain exclusive and non-exclusive licenses and an option to license Blaze's platform technology to use in conducting certain research and development activities. The Company made a one-time, non-refundable, upfront payment of $1.8 million to Blaze, as partial consideration for the rights and licenses granted to the Company under the Blaze Agreement, which was recognized immediately as research and development expense, as the acquired license represented IPR&D with no alternative future use. The Company paid an additional one-time payment of $0.2 million in connection with the December 19, 2022 amendment, which was recognized immediately as research and development expense. The Blaze Agreement requires the Company to make specified non-refundable, non-creditable discovery milestones milestone payments to Blaze of up to $0.7 million per collaboration target as well as royalty payments on a product-by-product basis until the later of (a) the date of expiration of the last-to-expire valid claim covering such collaboration target, or (b) ten years following the date of the first commercial sale of such collaboration target. The milestone payments will be recognized when the milestone is achieved, and the royalties will be recognized when the sales occur. As of December 31, 2025, no such milestones had been achieved.

Upon execution of the Blaze Agreement, the Company also issued the Preferred Stock Warrants to Blaze to purchase 2,000,000 shares of Partner Preferred Stock, as a partial consideration for the rights and licenses granted to the Company. The Preferred Stock Warrants will expire either upon a change of control or on July 22, 2031. The Preferred Stock Warrants represent an additional upfront payment and is treated in a similar manner to the one-time upfront payment. The initial fair value of the Preferred Stock Warrants of $0.6 million was recognized immediately as research and development expense for the year ended December 31, 2021. In connection with the amendment on May 20, 2022, the Company replaced the original terms of the Preferred Stock Warrants with revised vesting dates. As of December 31, 2023, 250,000 Preferred Stock Warrants were vested.

In March 2024, the Company notified Blaze of the termination of the Blaze Agreement. Upon termination, Blaze exercised the 250,000 of vested Preferred Stock Warrants for nominal consideration. The remaining unvested Preferred Stock Warrants were cancelled upon the notice of termination.

Institute for Protein Innovation, Inc. license agreement

On November 1, 2021, the Company entered into an exclusive license agreement (the "IPI Agreement") with the Institute for Protein Innovation, Inc. ("IPI") pursuant to which IPI granted to the Company an exclusive, worldwide license, with the right to sublicense (subject to certain conditions), on certain of IPI's patents and know-how related to certain binder proteins, targeting up to 14 target proteins, to research, develop, make, have made and commercialize certain products. The Company made a one-time upfront payment of $0.2 million and will make annual payments of less than $0.1 million on each anniversary up to the date of the first commercial sale of the first licensed product in order to retain the license, pursuant to which the Company has paid an aggregate of $0.2 million through December 31, 2025. The one-time upfront payment was recognized immediately as research and development expense, as the acquired license represented IPR&D with no alternative future use. Under the IPI Agreement, the Company is also required to pay non-refundable, non-creditable development and regulatory milestone payments of up to $24.0 million. In addition, if the Company successfully commercializes a licensed product under the IPI Agreement, the Company is required to pay low single-digit royalties on net sales, on a product-by-product and country-by-country basis, subject to specified reductions, until the later of (a) the expiration of the last to expire valid claim covering the manufacture, use or sale of such licensed product in such country or (b) ten years after the first licensed product sale in such country. The milestone payments will be recognized when the milestone is achieved, and the royalties will be recognized when the sales occur. As of December 31, 2025 and 2024, no such milestones have been achieved.

TRIUMF license agreement

On July 21, 2022, the Company entered into a license agreement (the "TRIUMF License") with TRIUMF Inc., a Canadian non-profit, TRIUMF Innovations Inc. ("TRIUMF"), a Canadian non-profit, University of British Columbia, and BC Cancer, a provincial health services authority, collectively referred to as the "Licensors." Pursuant to the TRIUMF License, the Licensors granted the Company a non-exclusive, worldwide license, with right to sublicense (subject to certain conditions), on certain patents and know-how related to the Licensors' chelator technology to make, use, sell, offer for sale, import, and export certain radiopharmaceutical products for the diagnosis, treatment, amelioration, and prevention of human diseases and conditions. None

of the Company's product candidates currently incorporate, or rely on, the licensed patents and know-how from the TRIUMF License.

The Company made a one-time upfront payment of $0.1 million which was recognized immediately as research and development expense, as the acquired license represented IPR&D with no alternative future use. The TRIUMF License requires the Company to pay up to an aggregate of $2.0 million upon achievement of certain regulatory and development milestones. The Company is also obligated to pay low single digit royalties on net sales of licensed products, on a product-by-product basis. For licensed products not covered by a valid claim of a licensed patent, our royalty obligation terminates on the tenth anniversary of the first commercial use of such licensed product in each country. The milestone payments will be recognized when the milestone is achieved, and the royalties will be recognized when the sales occur. As of December 31, 2025 and 2024, no such milestones have been achieved.

University of Minnesota license agreement

On March 3, 2023, the Company entered into an exclusive license agreement (the “Minnesota License”) with Regents of the University of Minnesota (the "University of Minnesota") under which the Company licensed certain rights to the licensed patents of a known target-binding miniprotein (the “Licensed Patents”) for commercialization throughout the term of the Minnesota License, pursuant to which the Company has paid an aggregate of $0.4 million through December 31, 2025. The Company made an initial payment of $0.1 million and will pay a yearly license fee of less than $0.1 million. The initial payment was recognized immediately as research and development expense, as the acquired license represented IPR&D with no alternative future use. The Company will make the non-refundable, non-creditable performance milestone payments to the University of Minnesota of up to an aggregate of $14.7 million upon achievement of certain regulatory and development milestones, subject to specified reductions upon regulatory approvals of the first therapeutic licensed product, and up to $35.0 million upon the achievement of certain commercial milestones. In the event that the Company is not developing a therapeutic licensed product and are only developing a diagnostic licensed product, the Company will be required to pay up to an aggregate of $1.5 million upon specified regulatory approvals for up to three diagnostic licensed products. In addition, the Company will make running royalty payments on a product-by-product basis based on a low single digit percentages of net sales, until expiration of the Minnesota License, which is when there is no longer a valid claim covering a licensed product, unless earlier terminated. The developmental milestone payment will be recognized when the milestone is achieved, and the commercial milestone payment and royalties will be recognized when the sales occur. No such milestones have been achieved.

In September 2025, the Company terminated the Minnesota License. No additional payment obligations on the Company's part or any other costs remain associated with the Minnesota License.

12. Collaboration revenue

Eli Lilly collaboration agreement

On May 16, 2024, the Company entered into the Collaboration Agreement with Eli Lilly to generate anticancer radiopharmaceuticals using the Company's novel miniprotein technology platform. Pursuant to the Collaboration Agreement, the Company granted Eli Lilly an exclusive (even as to the Company and its affiliates), royalty-bearing, worldwide license, with the right to sublicense, to certain of the Company's patents and other intellectual property rights to exploit certain compounds and therapeutic or diagnostic products that contain such compounds solely as products that contain a radioactive isotope. The Company also granted Eli Lilly a non-exclusive, royalty-bearing, worldwide license, with the right to sublicense, to the intellectual property necessary or useful to exploit the licensed compounds and licensed products solely as products that contain a radioactive isotope and a non-exclusive, fully paid-up license, with the right to sublicense, to exploit certain other intellectual property developed under the Collaboration Agreement for any and all purposes (subject to certain limitations). In addition, the Company and Eli Lilly agreed to negotiate in good faith to enter into a separate agreement in the event the parties agree that the clinical development of a licensed compound requires, or would be benefited by, a license to one of the Company's other compounds. Eli Lilly may, at any time in its sole discretion and without cause, terminate the Collaboration Agreement on a collaboration target-by-collaboration target or region-by- region basis (or any combination thereof) upon 60 days’ prior written notice to the Company. Eli Lilly may, in its sole discretion, terminate the Collaboration Agreement in its entirety at any time and without cause upon 60 days’ prior written notice to the Company.

Under the Collaboration Agreement, Eli Lilly may designate a specified number of initial collaboration targets, with one substitution right per initial collaboration target. The Company is responsible for research activities through initial human imaging studies for each selected target, and Eli Lilly will thereafter be responsible for regulatory filings, clinical development and commercialization activities worldwide. There is a separate research plan for each collaboration target, and the Company's development costs are capped, on a research plan-by-research plan basis. Eli Lilly will reimburse reasonable out-of-pocket costs and full-time employee equivalent costs incurred in excess of the cap.

The Collaboration Agreement requires Eli Lilly to pay $60.0 million as a nonrefundable upfront cash payment. The Collaboration Agreement requires Eli Lilly to pay up to an aggregate of $525.0 million upon achievement of certain research, development, regulatory and commercial launch milestones and up to an aggregate of $630.0 million upon achievement of certain sales milestones. In addition, if Eli Lilly successfully commercializes a therapeutic or diagnostic product under the Collaboration Agreement, Eli Lilly is required, unless earlier terminated, to pay the Company a tiered royalty of up to low-double digits based on annual net sales, on a product-by-product and country-by-country basis, subject to specified reductions, until the later of the expiration of licensed patent rights in a country, expiration of regulatory exclusivity, or ten years after the first product sale in such country.

The Company evaluated the Collaboration Agreement and determined it was within the scope of ASC 606. The Company determined the promised goods and services included the exclusive and non-exclusive license granted to Eli Lilly to use the Company's intellectual property and know-how to research, develop, and commercialize products related to each of the initial collaboration targets selected by Eli Lilly, as well as corresponding research activities to be provided by the Company during a specified research term for each of the collaboration targets. The Company determined that the exclusive license granted under the Collaboration Agreement and the research activities are not individually distinct and represents a combined performance obligation, one for each of the distinct initial collaboration targets.

Eli Lilly also has the right to replace each of the initial collaboration targets once during a specified period for additional consideration of reimbursement of the actual research costs incurred for each replaced initial collaboration target. The Company concluded the consideration to be paid by Eli Lilly for each replacement right represented a discount to the standalone selling price. Accordingly, the replacement right was determined to represent a material right and thus represents a performance obligation for each initial collaboration target. Therefore, there are two separate performance obligations for each initial collaboration target within the context of the Collaboration Agreement.

Concurrently, the Company also entered into the Series A-1 Agreement with Eli Lilly and issued 2,500,000 shares of Series A-1 Preferred Stock (see Note 7) to Eli Lilly for total proceeds of $10.0 million (the "Eli Lilly Equity Transaction"). The Company determined the fair value of the shares sold under the Eli Lilly Equity Transaction to be $1.8 million less than the total proceeds received of $10.0 million. The Company recorded the issuance of the Series A-1 Preferred Stock at fair value and, therefore, the excess proceeds received were included in the transaction price of the Collaboration Agreement, which, along with the non-refundable upfront payment of $60.0 million, was allocated to each of the initial collaboration targets and each replacement right. For each initial collaboration target, the allocated transaction price is being recognized as revenue over the total estimated period of performance. For each replacement right, the allocated transaction price will be recognized as revenue over the total estimated period of performance if the material right is exercised, or it will be recognized as revenue immediately upon expiration of the replacement right.

The transaction price was allocated to the performance obligation for each initial collaboration target and the material right to replace each of the initial collaboration targets on a relative stand-alone selling price basis using the expected cost plus a margin approach under ASC 606. In September 2025, the transaction price was adjusted to include $1.0 million in variable consideration, upon the achievement of the first milestone under the Collaboration Agreement, which was previously excluded based on the Company's evaluation of the constraint of estimated variable consideration. All other remaining milestones remained fully constrained and excluded from the transaction price.

The Company recognizes revenue related to each initial collaboration target over time using the costs incurred input method, such that revenue is recognized based on the Company's efforts or inputs to the satisfaction of a performance obligation, which provides an appropriate depiction of the Company's progress toward fulfilling its performance obligations. Through this method, the Company applies a cost-to-cost method and compares the actual costs incurred to date with the current estimate of total costs to complete ("ETCs") to measure the satisfaction of each performance obligation and recognize revenue as research activities progress and costs are incurred. Throughout the research term for each initial collaboration target, the Company monitors its ETCs to determine if an adjustment is needed to ensure that revenue is recognized proportionally for costs incurred to date relative to the total costs expected to be incurred for the total performance obligation. As there are changes in facts and circumstances that impact management's ETCs with respect to ongoing and prospective research activities, the ETCs are updated accordingly. The Company recognized $6.5 million of collaboration revenue for the year ended December 31, 2025. The remaining transaction price of $54.8 million is expected to be recognized as revenue through 2030. As of December 31, 2025, one development milestone under the Collaboration Agreement totaling $1.0 million was achieved.

13. Commitments and contingencies

Legal proceedings

The Company was not subject to any material legal proceedings during the years ended December 31, 2025 and 2024, and the Company is not aware of any material legal proceedings that are currently pending or threatened.

Royalty transfer agreement

On August 27, 2020, concurrent with entering into the Series Seed Agreement, the Company entered into a royalty transfer agreement (the "Royalty Transfer Agreement") with MPM Oncology Charitable Foundation, Inc. (the “MPM Charitable Foundation”), an affiliate of a stockholder holding more than 5% of the total outstanding stock of the Company, and the UBS Optimus Foundation (“UBS" and together with MPM Charitable Foundation, the “Charitable Foundations”). Pursuant to the Royalty Transfer Agreement, the Company will pay 0.5% of annual global net sales to each of the Charitable Foundations, for a total of 1.0% of net sales, subject to customary reductions, for products that incorporate or utilize intellectual property that was discovered or developed by the Company prior to an initial public offering. The Company's payment obligations for each product will continue on a country-by-country basis upon the later of the twelfth anniversary of the first commercial sale of such product in such country or the expiration of the last to expire of certain patents owned or controlled by the Company covering such products in such country.

The Company’s payment obligations to MPM Charitable Foundation will terminate immediately upon authorization of the MPM Charitable Foundation's board of directors (or similar body) or upon the winding up or dissolution of MPM Charitable Foundation. The Company’s payment obligations to UBS will terminate immediately upon the winding up of Oncology Impact Fund 2, L.P., a Cayman Islands exempt limited partnership which is affiliated with MPM Charitable Foundation.

The Company will record a liability when the associated net sales are generated.

14. Related party transactions

The Company has received consulting and management services from entities affiliated with MPM Asset Management LLC ("MPM"), a beneficial owner holding more than 5% of the total outstanding common stock of the Company as of December 31, 2025 and 2024. In connection with these services, the costs incurred for the year ended December 31, 2025 were de minimis, and the Company incurred costs of $0.1 million for the year ended December 31, 2024, which are included in general and administrative expenses on the consolidated statements of operations and comprehensive loss. As of December 31, 2025 and 2024, no amounts were owed to the MPM affiliates.

15.Employee Benefit Plans

Effective September 2021, the Company adopted the Aktis Oncology 401(k) Plan (the “401(k) Plan”) for its employees, which is designed to be qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. The Company did not provide any matching or discretionary contributions under the 401(k) Plan during the years ended December 31, 2025 and 2024.

16. Leases

Operating leases

In March 2021, the Company entered into a lease agreement for a research and development laboratory and related office space located in Durham, North Carolina (the "Durham Lease"). The term of the Durham Lease commenced in March 2021 and had an original termination date of March 31, 2024. During the year ended December 31, 2024, the Durham Lease was extended with a revised termination date of September 30, 2025. The lease was extended again in January 2025, with a revised termination date of September 30, 2026. The lease extensions were accounted for as modifications in accordance with ASC 842 and the Company reassessed the lease liability and right-of-use ("ROU") asset related to the lease at each modification date. The first lease extension resulted in an increase of $0.5 million to the related operating lease ROU asset and lease liability on the date of the extension. The second lease extension resulted in an increase of $0.4 million to the related operating lease ROU asset and lease liability on the date of the extension.

In January 2022, the Company entered into a lease for office, laboratory and storage space located in Boston, Massachusetts. Since the space was under construction, and certain improvements needed to be made before taking occupancy, the Company did not record a ROU asset or lease liability related to this lease until January 4, 2023, when the Company took control of the premises. In April 2025, the Company entered into an amendment to increase the lab space in the same building. The amendment provided for additional operating lease payments of $0.6 million for the additional lab space and includes annual base rent escalation clauses during the lease term. The lease is set to expire 10 years from the rent commencement date of January 4, 2023.

The following table presents weighted-average remaining lease term and discount rates which are used in the calculation of the Company's ROU assets and lease liabilities:

	December 31,	
	2025	2024
Weighted-average remaining lease term (in years)	6.87 years	7.70 years
Weighted-average discount rate	10.5%	11.0%

Components of lease costs are presented below (in thousands):

	Year Ended December 31,	
	2025	2024
Operating lease cost	$ 3,112	$ 3,349
Variable lease cost	803	732
Total lease cost	$ 3,915	$ 4,081

Maturity analysis of operating lease liabilities as of December 31, 2025, were as detailed below (in thousands):

2026	$ 2,437
2027	2,145
2028	2,173
2029	2,238
2030	2,304
2031 and beyond	5,020
Total undiscounted lease payments	16,317
Less: imputed interest	(4,769)
Total operating lease liabilities	$ 11,548

Other information related to leases was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Cash flows included in the measurement of lease liabilities:		
Cash paid for amounts included in the measurement of operating lease liabilities	$ 2,652	$ 2,901
Remeasurement of right-of-use asset and lease liability	$ 939	$ 131

17. Net loss per share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows for the periods presented (in thousands, except share and per share amounts):

	Year ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (63,731)	$ (43,980)
Net loss attributable to common stockholders, basic and diluted	$ (63,731)	$ (43,980)
Denominator:		
Weighted-average number of common stock used in net loss per share, basic and diluted	813,524	704,165
Net loss per share of common stock, basic and diluted	$ (78.34)	$ (62.46)

The Company's potentially dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common stock outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following outstanding

potentially dilutive securities have been excluded from the computation of diluted net loss per share attributable to common stockholders, as including them would have had an anti-dilutive effect:

	Year ended December 31,	
	2025	2024
Preferred Stock	34,057,218	34,057,218
Options to purchase common stock	5,899,875	5,283,340
Total	39,957,093	39,340,558

18. Segment information

The Company has one operating and reportable segment focused on the research and development of targeted radiopharmaceuticals to treat a broad range of solid tumor cancers. The accounting policies of the single operating segment are identical to those described in Note 2. The CODM manages the Company's operations on a consolidated basis and assesses performance based on consolidated net loss, which is reported on the consolidated statements of operations. The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets. Expenditures for additions to long-lived assets, which include purchases of property and equipment, are included in total consolidated assets reviewed by the CODM and are reported on the consolidated statements of cash flows. The CODM uses consolidated net loss and budget-to-actual variances to allocate resources and assess the performance of the entire company.

Certain segment information for prior period has been recast to conform to the current year presentation. The recast did not impact the Company's previously reported consolidated results of operations.

The following information represents significant segment expenses regularly provided to the CODM with the following categories (in thousands):

	Year ended December 31,	
	2025	2024
Collaboration revenue	$ 6,497	$ 1,487
Research and development expenses:		
Employee-related	(20,427)	(13,344)
Consulting and contractor	(1,145)	(1,335)
External research and development	(31,481)	(14,827)
Laboratory supplies	(3,744)	(3,418)
Scientific advisory board	(97)	(87)
Information technology, facilities, office and other [1]	(10,557)	(7,943)
General and administrative expenses:		
Employee-related	(5,212)	(4,948)
Consulting and contractor	(1,842)	(1,749)
Legal and professional services	(2,612)	(3,252)
Information technology, facilities, office and other [1]	(4,064)	(2,634)
Other segment items [2]	10,953	8,070
Net loss	$ (63,731)	$ (43,980)

[1] IT, facilities, office and other includes depreciation, amortization, stock-based compensation expense, and allocations.

[2] Other segment items consist of interest income and other expense, net. Interest income consists of interest earned on cash equivalents and marketable securities and amortization or accretion of discounts or premiums on marketable securities. Other expense, net consists of gains and losses on currency revaluation related to the payment of foreign vendor invoices.

19. Subsequent events

2026 Equity Plans

In January 2026, the Board and the Company's stockholders adopted and approved the 2026 Stock Option and Incentive Plan (the "2026 Plan"), which became effective on January 8, 2026, the date immediately preceding the date that the registration statement on Form S-1 for the Company's IPO was declared effective by the SEC. The 2026 Plan initially reserved 4,009,452 shares of common stock for future issuances and is subject to automatic increases in the number of shares of common stock reserved for future issuances in accordance with the evergreen provisions in the 2026 Plan. The shares reserved for future issuance under the 2020 Plan ceased to be available for issuance at the time the 2026 Plan became effective. Any shares underlying outstanding stock

awards granted under the 2020 Plan that subsequently expire or are repurchased, forfeited, cancelled, or withheld will return to the 2026 Plan and be reserved and available for issuance. The Company granted 1,720,277 of common stock options subject to service-based vesting to certain executive officers, directors, and employees at the time of effectiveness of the 2026 Plan with an exercise price equal to $18.00 per share.

In January 2026, the Board and the Company's stockholders adopted and approved the 2026 Employee Stock Purchase Plan (the "2026 ESPP"), which became effective on January 8, 2026, the date immediately preceding the date that the registration statement on Form S-1 for the Company's IPO was declared effective by the SEC. The 2026 ESPP initially reserved 27,843 shares of common stock for future issuance and is subject to automatic increases in the number of shares of common stock reserved for future issuances in accordance with the evergreen provisions in the 2026 ESPP.

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

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, 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.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Annual Report. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of December 31, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting.

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

Attestation Report of the Registered Public Accounting Firm.

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

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Rule 10b5-1 Trading Arrangements

From time to time, our officers (as defined in Rule 16a–1(f)) and directors may enter into Rule 10b5-1 or non-Rule 10b5-1 trading arrangements (as each such term is defined in Item 408 of Regulation S-K). During the quarter ended December 31, 2025, none of our officers or directors adopted or terminated any such trading arrangements.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table provides information regarding our current executive officers and directors, including their ages as of March 10, 2026:

Name	Age	Position(s)
Executive officers		
Matthew Roden, PhD	55	President, Chief Executive Officer and Director
Kyle D. Kuvalanka	57	Chief Financial Officer
Akos Czibere, MD, PhD	48	Chief Medical Officer
Paul L. Feldman, PhD	65	Chief Scientific Officer
Shulamit Ron-Bigger, PhD	45	Chief Operating Officer
Tyler Benedum, PhD	50	Chief Technical Officer
Non-employee directors		
Todd Foley, MBA[(2)(3)]	54	Chair of the Board of Directors
Ken Herrmann, MD[(3)]	48	Director
Helen S. Kim, MBA[(3)]	63	Director
Oleg Nodelman	49	Director
Lloyd M. Segal, MBA[(1)(3)]	62	Director
Michael A. Sherman, MBA[(1)(2)]	59	Director
Mary Thistle[(1)(2)]	66	Director

(1) Member of the audit committee.
(2) Member of the compensation committee.
(3) Member of the nominating and corporate governance committee.

Executive officers

Matthew Roden, PhD has served as our President and Chief Executive Officer and as a member of our board of directors since September 2020. Since August 2020, Dr. Roden has worked as an Entrepreneur Partner at MPM BioImpact LLC, a biotechnology investment firm. Dr. Roden also serves as a member of the board of directors of Orna Therapeutics, Inc., a biotechnology company, since May 2024 following its acquisition of ReNAgade Therapeutics Inc. where he had served on the board of directors since January 2023. Previously, Dr. Roden served on the board of directors of NextPoint Therapeutics, Inc., a clinical-stage biotechnology company, from October 2020 to December 2024, iTeos Therapeutics, Inc. (Nasdaq: ITOS), a clinical-stage biopharmaceutical company, from November 2020 to February 2023, and as Chairman of Tumeric Acquisition Corporation, a special purpose acquisition company, from September 2020 to December 2022. From November 2019 to August 2020, he was Senior Vice President and Head of Enterprise Strategy at Bristol Myers Squibb, a global pharmaceutical company. From May 2016 to November 2019, he served as Head of Strategic Corporate Development, accountable for mergers and acquisitions, structured transactions, strategic equity investing, and divestitures, and concurrently served as Head of Global Business Development Assessment at Bristol Myers Squibb, leading business development search and evaluation activities for all therapeutic categories. Dr. Roden also previously worked as an equity research analyst at UBS Investment Bank and J.P. Morgan. Dr. Roden holds a PhD in Microbiology and Immunology from the Albert Einstein College of Medicine, an MS from Georgetown University, a BS from George Mason University and was a pre-doctoral fellow at the National Cancer Institute. We believe that Dr. Roden's leadership experience spanning both the pharmaceutical and financial industries qualifies him to serve as on our board of directors.

Kyle D. Kuvalanka has served as our Chief Financial Officer since November 2025. Mr. Kuvalanka previously served as Chief Financial Officer and Chief Business Officer of ROME Therapeutics, Inc. since November 2023. Prior to ROME Therapeutics, from April 2020 to April 2023, he served as the Chief Financial Officer and Chief Operating Officer of Goldfinch Bio, Inc., or Goldfinch. In January 2023, Goldfinch initiated an Assignment for the Benefit of Creditors pursuant to Delaware state law. From April 2021 until September 2023, Mr. Kuvalanka served as a member of the board of directors and audit chair of IMV Inc., or IMV, a clinical stage biopharmaceuticals company. In December 2023, IMV filed an assignment pursuant to section 49(1) of the Bankruptcy and Insolvency Act (Canada) voluntarily declaring bankruptcy. Previously, Mr. Kuvalanka served as the Chief Operating Officer and Principal Financial and Accounting Officer of Syros Pharmaceuticals (Nasdaq: SYRS) and Chief Business Officer and Principal Financial and Accounting Officer of Blueprint Medicines Corporation (Nasdaq: BPMC). From 2002 to September 2013, Mr. Kuvalanka worked at Takeda Pharmaceuticals and at Millennium prior to its takeover by Takeda, including

as vice president, corporate strategy, business development and alliance management from 2009 to September 2013. Mr. Kuvalanka holds a BA from Wesleyan University and an MBA from The Wharton Business School of the University of Pennsylvania.

Akos Czibere, MD, PhD has served as our Chief Medical Officer since July 2024. From April 2017 through July 2024, Dr. Czibere held increasing roles of responsibility at Pfizer, most recently serving as Vice President Therapeutic Area Head of Hematology —Oncology, where he was responsible for strategy and execution across multiple programs. Prior to that, Dr. Czibere held increasing levels of seniority at Merrimack Pharmaceuticals. Dr. Czibere holds an MD and PhD from the University of Duesseldorf, Germany. Dr. Czibere conducted a Postdoctoral Fellowship at Harvard Medical School.

Paul L. Feldman, PhD has served as our Chief Scientific Officer since December 2020. Previously, Dr. Feldman was the Co-Founder and Chief Executive Officer of Phoundry Pharmaceuticals, Inc. before it was acquired by Intarcia Therapeutics, Inc., a biopharmaceutical company, in 2015. Dr. Feldman then spent five years at Intarcia on the executive management team as Head of Discovery and Translational Medicine leading the discovery and development of novel peptide therapeutics to treat metabolic disease until December 2020. Prior to his roles at Phoundry and Intarcia, he worked more than 27 years at GlaxoSmithKline (NYSE: GSK), a multinational pharmaceutical and biotechnology company, where he was part of the discovery of five approved drugs. Dr. Feldman also serves on the board of directors of the Chordoma Foundation. Dr. Feldman holds a PhD in Chemistry from the University of California, Berkeley and BS in Chemistry from Duke University.

Shulamit Ron-Bigger, PhD has served as our Chief Operating Officer since September 2022. Previously, Dr. Ron-Bigger served as the Vice President, Portfolio Strategy for the Research and Early Development organization at Bristol Myers Squibb, from March 2021 until September 2022, where she led portfolio and program strategy, budget management, and operating model design and its implementation. Dr. Ron-Bigger also held various strategic and commercial roles in both United States and global markets while at Bristol Myers Squibb beginning in November of 2017. Prior to her roles at Bristol Myers Squibb, she worked as a strategic consultant to large pharmaceutical companies and served as a Human Resource officer in the Israeli Defense Forces. Dr. Ron-Bigger holds a PhD in Cancer Epigenetics from The Hebrew University of Jerusalem and a BA in Molecular Biochemistry from Technion – Israel Institute of Technology.

Tyler Benedum, PhD has served as our Chief Technical Officer since May 2024, prior to which he served as our Senior Vice President, CMC since January 2022. Previous to joining Aktis, from August 2005 to January 2022, Dr. Benedum held positions of increasing seniority at Avid RadioPharmaceuticals Inc. (acquired by Eli Lilly and Company), most recently serving as its Vice President of CMC Development and Manufacturing. Dr. Benedum received a BS in Chemistry from Washington College and a PhD in Organic Chemistry from the University of Virginia. He then completed his Postdoctoral Fellowship in natural product synthesis at the University of Pittsburgh.

Non-employee directors

Todd Foley, MBA is our co-founder and has served as Chair of our board of directors since August 2020. Since 1999, Mr. Foley has worked at MPM BioImpact LLC, a biotechnology investment firm where he has served as a Managing Director focusing on venture investments in biotech companies. Mr. Foley has previously served on the board of directors of Entrada Therapeutics, Inc. (Nasdaq: TRDA), from December 2018 to June 2023, Repare Therapeutics Inc. (Nasdaq: RPTX), from June 2017 to June 2024, Rhythm Pharmaceuticals, Inc. (Nasdaq: RYTM), from 2014 to June 2021, and Chiasma Inc., from May 2008 until its merger with Amryt Pharma plc in August 2021. Mr. Foley also serves on the board of directors of several other privately-held life sciences and biotechnology companies. Mr. Foley received a BS in Chemistry from the Massachusetts Institute of Technology and an MBA from Harvard Business School. We believe that Mr. Foley's financial expertise and experience as both an investor of and a member of the board of directors of numerous life sciences companies qualifies him to serve on our board of directors.

Ken Herrmann, MD has served as a member of our board of directors since May 2024. Since 2016, Dr. Herrmann has been the Director and Chair of the Department of Nuclear Medicine at the Universitätsmedizin Essen in Germany. Prior to that, Dr. Herrmann was a tenured Associate Professor at the Department of Molecular and Medical Pharmacology at the University of California, Los Angeles, from 2015 until June 2021. Dr. Herrmann also served as the Chair of the EANM Oncology & Theranostics Committee and on the board of directors of two privately-held biotechnology companies. Currently he serves as a Section Editor of the Journal of Nuclear Medicine and as Imaging Editor of European Eurology. Dr. Herrmann received an MD and a Doctorate degree in Medicine from the Humboldt Universität Berlin and an MBA from the University of Zurich. We believe that Dr. Herrmann's expertise and experience as a professor in medicine at numerous higher education institutions qualifies him to serve on our board of directors.

Helen S. Kim, MBA has served as a member of our board of directors since February 2021. Since April 2019, Ms. Kim has been a Senior Managing Director of Vida Ventures, LLC, a venture capital firm. From March 2018 to March 2019, Ms. Kim was a Partner at The Column Group, a venture capital firm. Previously, Ms. Kim was the Executive Vice President, Business Development at Kite Pharma, Inc. from June 2014 to January 2018, where she led the business and corporate development initiatives resulting in its acquisition by Gilead in 2017. From August 2009 to November 2014, Ms. Kim worked at NGM Biopharmaceuticals Inc., a biopharmaceutical company, serving in the role of Chief Business Officer from August 2009 to July 2012 and Strategic

Advisor from July 2012 to November 2014. From 2007 to 2008, she served as the Chief Executive Officer and President of Kosan Biosciences Inc., a pharmaceutical company, prior to the sale of the company to Bristol Myers Squibb. Prior to this, Ms. Kim held various executive and leadership positions at Affymax, Inc., a biopharmaceutical company, Onyx Pharmaceuticals, Inc., a biopharmaceutical company and subsidiary of Amgen Inc., Protein Design Labs, Inc., a technology company, and Chiron Corporation, a biotechnology company and a subsidiary of Novartis AG. From August 2003 to November 2007, Ms. Kim also served as Chief Program Officer for the Gordon and Betty Moore Foundation, a nonprofit organization. Ms. Kim currently serves on the board of directors of Phylaxis Bioscience, LLC, since September 2024, Prothena Corporation plc (Nasdaq: PRTA), since August 2022, and on the board of directors of the privately held companies, InduPro Labs, since February 2022, Protego Biopharma, since October 2021, IconOVir Bio, Inc., since December 2020, ReCode Therapeutics, Inc., since March 2020, and A2 Biotherapeutics, Inc., since April 2019. Ms. Kim previously served on the board of directors of Applied Molecular Transport, Inc., from October 2018 until April 2022. Ms. Kim received a BS in Chemical Engineering from Northwestern University and an MBA from the University of Chicago. We believe that Ms. Kim's business and leadership experience at numerous life sciences companies qualifies her to serve on our board of directors.

Oleg Nodelman has served as a member of our board of directors since February 2021. Since October 2012, Mr. Nodelman has served as the Founder and Portfolio Manager of EcoR1 Capital, LLC, a biotechnology-focused investment advisory firm which invests in companies in all stages of research and development. From 2001 to 2012, he held various roles including Portfolio Manager at BVF Partners. Mr. Nodelman has served as a director of the biotechnology companies, AnaptysBio, Inc. (Nasdaq: ANAB) since April 2021, Galapagos NV (Nasdaq: GLPG) since October 2024 and Zymeworks Inc. (Nasdaq: ZYME) since February 2025. Previously, Mr. Nodelman served as a director of the biotechnology companies Nuvation Biosciences, Inc. (Nasdaq: NUVB) from February 2021 to December 2023 and Prothena Corporation plc from December 2019 to December 2024. Mr. Nodelman also served as a director of Panacea Acquisition Corp. II, a blank check company, from April 2020 to February 2021. Mr. Nodelman earned his BS in Foreign Service with a concentration in Science and Technology from Georgetown University. We believe Mr. Nodelman's extensive biotechnology industry experience qualifies him to serve on our board of directors.

Lloyd M. Segal, MBA has served as a member of our board of directors since February 2021. Mr. Segal is the co-founder of Repare Therapeutics, Inc., a clinical-stage oncology drug developer, and served as its President and Chief Executive Officer and as a member of the board of directors, since its incorporation in 2016 through April 2025. From February 2010 to January 2016, he was a Managing Partner with Persistence Capital Partners, a leading healthcare private equity investor. From June 2016 to March 2020, Mr. Segal served as Entrepreneur-in-Residence with Versant Ventures, a biotechnology venture capital firm based in San Francisco. Previously, Mr. Segal served as chief executive officer of several emerging biotechnology companies including Caprion Pharmaceuticals (now CellCarta), Advanced Bioconcept and Thallion Pharmaceuticals. Mr. Segal previously served as Chairman of LMC Diabetes & Endocrinology, North America's largest community endocrinology and diabetes clinical and research practice, and Chairman of MedReleaf, until its $2.5 billion sale to Aurora Cannabis in 2018. He also previously served on the boards of directors of several public and private U.S. and Canadian companies. Mr. Segal received a BA in Politics from Brandeis University and an MBA from Harvard Business School. We believe that Mr. Segal's extensive experience in the biotechnology industry in addition to his corporate governance and executive leadership experience qualifies him to serve on our board of directors.

Michael A. Sherman, MBA has served as a member of our board of directors since August 2025. Mr. Sherman currently serves on the board of directors of Werewolf Therapeutics, Inc. (Nasdaq: HOWL), a publicly traded biopharmaceutical company, a position he has held since May 2021. Mr. Sherman previously served from April 2019 to July 2023 as Chief Executive Officer and a member of the board of directors of Chimerix, Inc., a publicly traded biopharmaceutical company, and as chair of the board of directors of Chimerix from August 2023 to April 2025. Prior to that, Mr. Sherman served as President, Chief Executive Officer, and member of the board of directors of Endocyte, Inc., a biopharmaceutical company, from June 2016 until December 2018, when it was acquired by Novartis. Mr. Sherman joined Endocyte in 2006 and served as its Chief Financial Officer and Chief Operating Officer prior to becoming Chief Executive Officer. Prior to joining Endocyte, Mr. Sherman served in various executive roles, including as vice president of finance and strategic planning for Guidant Corporation, which was acquired by Boston Scientific Corporation. He has also served on the board of directors of Biospecifics Technologies, Inc. from April 2020 until its acquisition by Endo Pharmaceuticals in December 2020, and he served as chair of the board of directors of the Children's Museum of Indianapolis from January 2012 until December 2022. Mr. Sherman holds a BA in economics from DePauw University and an MBA from the Tuck School of Business at Dartmouth, graduating as a Tuck Scholar. We believe that Mr. Sherman's 30 years' experience advancing therapeutics to commercial launch and expertise in operations and strategic transactions in the biotechnology and medical technology industries qualifies him to serve as a member of our board of directors.

Mary Thistle has served as a member of our board of directors since January 2025. Ms. Thistle previously served as Special Advisor to the Bill & Melinda Gates Medical Research Institute, or the Medical Research Institute, a non-profit biotech organization, from the fall of 2020 to June 2022, and previously served as the organization's Chief of Staff from January 2018 to the fall of 2020. Prior to the Medical Research Institute, she held senior leadership positions at Dimension Therapeutics, Inc., a gene therapy company, including as Chief Operating Officer from 2016 to 2017 and Chief Business Officer from 2015 to 2016. Prior to joining Dimension Therapeutics, Ms. Thistle held various leadership positions at Cubist Pharmaceuticals, Inc., a biopharmaceutical company, including as Senior Vice President, Business Development from 2014 to 2015, Vice President,

Business Development from 2012 to 2013 and Senior Director, Business Development from 2009 to 2012. Prior to Cubist Pharmaceuticals, she held various positions at ViaCell, Inc. and PerkinElmer LAS Inc. Ms. Thistle has served on the board of directors of Cullinan Therapeutics, Inc. (Nasdaq: CGEM), since August 2024, Q32 Bio Inc. (Nasdaq: QTTB) (formerly known as Homology Medicines, Inc.), since March 2024, Entrada Therapeutics, Inc., since May 2021 and Vigil Neuroscience, Inc., since April 2022, as well as on the boards of multiple private companies. Ms. Thistle also previously served on the board of directors of Alaunos Therapeutics, Inc. (formerly known as Ziopharm Oncology, Inc.) from November 2020 to December 2023. Ms. Thistle holds a BS in Business and Accounting from the University of Massachusetts, Boston and is a former Certified Public Accountant. We believe Ms. Thistle is qualified to serve as a member of our board of directors due to her finance and business development background and biotechnology industry experience.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Board Composition

Our business and affairs are managed under the direction of our board of directors, which currently consists of eight members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Our board of directors may establish the authorized number of directors from time to time by resolution. In accordance with our amended and restated certificate of incorporation, our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors are divided among the three classes as follows:

- Class I consists of Todd Foley, Helen S. Kim and Oleg Nodelman, and their terms will expire at our annual meeting of stockholders to be held in 2027;
- Class II consists of Lloyd M. Segal and Mary Thistle, and their terms will expire at our annual meeting of stockholders to be held in 2028; and
- Class III consists of Ken Herrmann, Michael A. Sherman and Matthew Roden, and their terms will expire at our annual meeting of stockholders to be held in 2029.

Our amended and restated bylaws provides that the authorized number of directors may be changed only by resolution approved by a majority of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change of control. Our directors may be removed for cause by the affirmative vote of the holders of at least two-thirds of our voting stock.

Board Leadership Structure

Our board of directors is currently chaired by Todd Foley, who has authority, among other things, to call and preside over board of directors meetings, to set meeting agendas and to determine materials to be distributed to the board of directors. Accordingly, the Chairperson has substantial ability to shape the work of the board of directors. We believe that separation of the positions of Chairperson and Chief Executive Officer reinforces the independence of the board of directors in its oversight of our business and affairs. In addition, we have a separate chair for each committee of our board of directors. The chair of each committee is expected to report annually to our board of directors on the activities of their committee in fulfilling their responsibilities as detailed in their respective charters or specify any shortcomings should that be the case.

Role of the Board in Risk Oversight

Our board of directors and its committees have an active role in overseeing the management of our risks. Our board of directors is responsible for general oversight of risks and regular review of information regarding our risks, including credit risks, liquidity risks and operational risks. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation plans and arrangements. The audit committee is responsible for overseeing the management of risks relating to accounting matters and financial reporting, as well as risks relating to cybersecurity matters. The nominating and governance committee is responsible for overseeing the management of risks associated with the independence of our board of directors and potential conflicts of interest. Although each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board of directors is regularly informed through discussions from committee members about such risks.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee has adopted a written charter that satisfies the application rules and regulation of the SEC and the rules of the Nasdaq Stock Market, or the Nasdaq Listing Rules, which are posted on our website at www.aktisoncology.com. Our board of directors may establish other committees as it deems necessary or appropriate from time to time. Information contained on, or accessible through, our website is not a part of this Annual Report, and the inclusion of our website address in this Annual Report is only an inactive textual reference.

Audit Committee

The audit committee's responsibilities include, among others:

- appointing, retaining, terminating, approving the compensation of, and evaluating the qualifications, performance, procedures and independence of, our independent registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of written periodic reports and resolving disagreements between management and such firm;
- pre-approving all audit and permitted non-audit services to be performed by our independent registered public accounting firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures, including earnings releases;
- overseeing and periodically reviewing with our independent registered public accounting firm our compliance with all applicable requirements of the Public Company Accounting Oversight Board;
- making recommendations to the board of directors to take appropriate action in response to the disclosures and statements made within the written periodic reports and discussions with the independent registered accounting firm to satisfy itself of such firms' independence;
- reviewing and discussing with management and our independent registered public accounting firm any material issues regarding accounting principles and financial statement presentations and the steps taken to deal with such issues;
- reviewing disclosures about any significant deficiencies or material weaknesses in our internal control structures and procedures, including disclosures in our annual and quarterly reports;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures, code of business conduct and ethics, procedures for complaints and legal and regulatory matters;
- reviewing and discussing with management and our independent registered public accounting firm any material issues regarding cybersecurity risks and processes for assessing, identifying and managing material risks from cybersecurity threats;
- reviewing and discussing our risk management policies, including with respect to our enterprise, financial, legal privacy and regulatory risk assessment and risk exposures;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management;
- reviewing and approving any related person transactions;
- overseeing our guidelines and policies governing risk assessment and risk management;
- overseeing and periodically reviewing the integrity of our information technology systems, process and data;
- preparing the audit committee report required by the rules of the SEC;
- reviewing and assessing, at least annually, the adequacy of the audit committee's charter; and
- performing, at least annually, an evaluation of the performance of the audit committee.

All audit services and all non-audit services, other than de minimis non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

The members of our audit committee are Mary Thistle, Lloyd M. Segal and Michael A. Sherman. Mary Thistle chairs the audit committee. Our board of directors has determined that each member of our audit committee is independent and has sufficient knowledge in financial and auditing matters to serve on the audit committee under the Nasdaq Listing Rules. Our board of directors has also determined that Mary Thistle is an "audit committee financial expert," as defined under Item 407 of Regulation S-K.

We believe that the composition and functioning of our audit committee complies with all applicable requirements of the Sarbanes-Oxley Act of 2022, or the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq Listing Rules and regulations.

Compensation Committee

Our compensation committee's responsibilities include, among others:

- developing and implementing our overall compensation strategy to ensure the attraction and retention of key management personnel, the motivation of management to achieve our corporate goals and strategies and the alignment of the interests of management with the long-term interests of our stockholders;
- reviewing and approving performance goals and objectives relevant to compensation of our chief executive officer and other executive officers;
- evaluating the performance of the chief executive officer and executive officers in light of their performance goals and objectives, including during executive sessions of non-employee directors, and recommending to our board of directors the compensation of our chief executive officer and other executive officers;
- reviewing and making recommendations to the board of directors with respect to non-employee director compensation;
- reviewing, overseeing and administering our equity incentive plans, granting awards under such plan and making recommendations to the board of directors about the adoption of any new or modifying existing equity-based, cash-based, management incentive and deferred compensation plans;
- establishing and reviewing "clawback" policies that allow the recouping of incentive compensation;
- reviewing, considering and selecting, to the extent determined to be advisable, a peer group of appropriate companies for purposing of benchmarking and analysis of compensation for our executive officers and non-employee directors;
- recommending to our board of directors any stock ownership guidelines for our executive officers and non-employee directors, periodically assessing these guidelines and recommending revisions as appropriate, and monitoring individual compliance with these guidelines;
- retaining, appointing or obtaining advice of a compensation consultant, legal counsel or other advisor and determining the compensation and independence of such consultant or advisor;
- preparing, if required, the compensation committee report on executive compensation for inclusion in our Annual Report on Form 10-K and our proxy statement in accordance with SEC rules;
- monitoring our compliance with the requirements of the Sarbanes-Oxley Act relating to loans to directors and officers;
- reviewing and approving all employment contract and other compensation, severance and change-in-control arrangements for our executive officers;
- establishing and periodically reviewing policies and procedures with respect to perquisites as they relate to our executive officers;
- reviewing the risks associated with our compensation policies and practices;
- overseeing the maintenance and presentation to our board of directors of management's plans for succession to senior management positions based on guidelines developed and recommended to the compensation committee to the full board of directors;
- reviewing our strategies, initiatives and programs with respect to our culture, talent recruitment, development, and retention, employee engagement and diversity and inclusion;
- maintaining minutes of the compensation committee and reporting its actions and any recommendations to the board of directors on a periodic basis;
- reviewing and assessing, at least annually, the adequacy of the compensation committee's charter; and

- performing, on an annual basis, an evaluation of the performance of the compensation committee.

The members of our compensation committee are Todd Foley, Michael A. Sherman and Mary Thistle. Todd Foley chairs the compensation committee.

We believe that the composition and functioning of our compensation committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq Listing Rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee's responsibilities include, among others:

- recommending to our board of directors the criteria for board and committee membership, including a description of the specific qualifications the nominating and corporate governance committee believes directors should possess, and periodically reassessing such criteria;
- recommending to our board of directors the persons to be nominated for election as directors and to each committee of the board;
- establishing policies and procedures to be followed under which our stockholders may recommend a candidate to the nominating and corporate governance committee for consideration for nomination as a director;
- establishing a process for identifying and evaluating nominees for election to the board, including nominees recommended by stockholders;
- reviewing and recommending committee slates on an annual basis;
- recommending to our board of directors qualified candidates to fill vacancies on our board of directors;
- developing and recommending to our board of directors a set of corporate governance principles applicable to us and reviewing the principles periodically;
- reviewing and making recommendations to our board with respect to our board size, composition, leadership structure and board committee structure;
- reviewing, in concert with our board of directors, our policies with respect to significant issues of corporate public responsibility, including but not limited to sustainability, diversity and inclusion and environmental, social and governance initiatives;
- making recommendations to our board of directors of processes for annual evaluations of the performance of our board of directors and committees of our board of directors;
- overseeing the process for annual evaluations of our board of directors and its committees, including individual directors and our management;
- considering and reporting to our board of directors any questions of possible conflicts of interest of members of our board of directors;
- reviewing with management the company's social corporate responsibility activities, policies, and program;
- providing new director orientation and continuing education for existing directors on a periodic basis;
- overseeing the maintenance and presentation to our board of directors of management's plans for succession to senior management positions in the company;
- reviewing and assessing, at least annually, the adequacy of the nominating and corporate governance committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the nominating and corporate governance committee.

The members of our nominating and corporate governance committee are Todd Foley, Ken Herrmann, Lloyd M. Segal and Helen S. Kim. Todd Foley chairs the nominating and corporate governance committee.

We believe that the composition and functioning of our nominating and corporate governance committee complies with all applicable requirements of the Sarbanes-Oxley Act, and all applicable SEC and Nasdaq Listing Rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

Director Nominations

No material changes have been made to the procedures by which our stockholders may recommend nominees to our board of directors from those that were described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on January 9, 2026.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of the Code of Conduct is available on our website at www.aktisoncology.com. We intend to disclose on our website any future amendments of our Code of Conduct or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors from provisions in the Code of Conduct. Information contained on, or that can be accessed through, our website is not incorporated by reference into this Annual Report. We have included our website in this Annual Report solely as an inactive textual reference.

Insider Trading Policy

We have adopted an Insider Trading Policy governing the purchase, sale, and other dispositions of our securities that applies to our directors, officers, employees, and other covered persons. We believe that our Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and the exchange listing standards applicable to us. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report.

Item 11. Executive Compensation.

This section describes the material elements of the compensation awarded to, earned by, or paid to our President and Chief Executive Officer, Matthew Roden, PhD, and our next two most highly compensated executive officers, Akos Czibere, MD, PhD, our Chief Medical Officer, and Paul L. Feldman, PhD, our Chief Scientific Officer, for our fiscal year ended December 31, 2025. These executives are collectively referred to as our named executive officers.

Summary Compensation Table

The following table sets forth the compensation awarded to, earned by, or paid to our named executive officers in respect of their service to us for the fiscal year ended December 31, 2025:

Name and Principal Position	Year	Salary ($)	Nonequity incentive plan compensation ($)[1]	Option Awards ($)[2]	All other compensation ($)	Total ($)
Matthew Roden, PhD						
President and Chief Executive Officer	2025	$ 579,280	$ 334,200	$ —	$ 1,200	$ 914,680
Akos Czibere, MD, PhD						
Chief Medical Officer	2025	$ 468,000	$ 106,650	$ 225,750	$ 102,280	$ 902,680
Paul L. Feldman, PhD						
Chief Scientific Officer	2025	$ 447,200	$ 194,015	$ —	$ 1,200	$ 642,415

(1) The amounts shown in this column represent annual bonuses earned with respect to fiscal year 2025 under our annual bonus program.
(2) The amounts reported in this column represent the aggregate grant date fair value of stock awards and option awards granted to the named executive officers during 2025, as calculated in accordance with FASB ASC Topic 718. Such grant date value does not take into account any estimated forfeitures related to service-based vesting conditions. The assumptions used in the grant date fair value of the awards in this column are described in Note 9—"Stock-Based Compensation" to our consolidated financial statements included elsewhere in this Annual Report.

Narrative Disclosure to Summary Compensation Table

Employment Arrangements With Our Named Executive Officers

Prior to the closing of the IPO, we had entered into executive employment agreements with each of our named executive officers. Each employment agreement provided for "at-will" employment and the compensation and benefits described below. In connection with the IPO, we entered into a new employment agreements with each of our named executive officers that became effective as of the closing of the IPO.

Matthew Roden, PhD

We entered into a letter agreement with Dr. Roden, dated September 24, 2021, which was effective as of May 1, 2021, pursuant to which he agreed to serve as our President and Chief Executive Officer. The letter agreement provided for at-will employment and either party had the ability to terminate his employment, for any reason or no reason, upon 30 days prior written notice, although we could terminate his employment for cause (as defined in the letter agreement) at any time upon written notice.

The letter agreement provided that Dr. Roden was entitled to an initial annualized base salary of $400,000, which reflected his initial 80% time commitment, which was subsequently increased to $557,000 in December 2024 to reflect his increased time commitment. The base salary is reviewed annually, typically in connection with our annual performance review process and may be adjusted from time to time to realign salaries with market levels. The letter agreement also provided that Dr. Roden was entitled to an annual discretionary bonus, with a target of 40% of his base salary. Dr. Roden was generally required to remain employed with us through the date of payment in order to earn a discretionary bonus for a fiscal year, but if, after the end of a fiscal year but prior to payment of the bonus for such fiscal year, we terminated his employment without cause, he resigned for good reason (as defined in the letter agreement) or his employment terminated due to his death or disability (as defined in the letter agreement), he would be deemed to have earned the bonus for such prior year as if he had remained employed by us through the payment date.

Akos Czibere, MD, PhD

We entered into a letter agreement with Dr. Czibere, dated June 18, 2024, pursuant to which he agreed to serve as our Chief Medical Officer. The letter agreement provided for at-will employment and either party had the ability to terminate his employment, at any time, for any reason or no reason.

The letter agreement provided that Dr. Czibere was entitled to an initial annualized base salary of $450,000 and also provided that Dr. Czibere was entitled to an annual discretionary bonus, with a target of 40% of his base salary. The base salary is reviewed annually, typically in connection with our annual performance review process and may be adjusted from time to time to realign salaries with market levels. Dr. Czibere was generally required to remain employed with us through the date of payment in order to earn a discretionary bonus for a fiscal year, but if, after the end of a fiscal year but prior to payment of the bonus for such fiscal year, we terminated his employment without cause (as defined in the letter agreement), he resigned for good reason (as defined in the letter agreement) or his employment terminated due to his death or disability (as defined in the letter agreement), he would be deemed to have earned the bonus for such prior year as if he had remained employed by us through the payment date.

Dr. Czibere received options to purchase 271,218 shares of our common stock pursuant to our 2020 Equity Incentive Plan. The options vest over a period of four years, with 25% of the shares subject to the option vesting on the first anniversary of his start date and the remaining shares vesting in equal monthly increments over the following 3 years, subject to continued service with us through the applicable vesting date. In addition, Dr. Czibere received a sign-on bonus of $100,000, with 50% payable six months after his start date and the remaining 50% payable upon his one year anniversary, subject to forfeiture in the event that Dr. Czibere employment was terminated within the first year without cause or for good reason (each as defined in the letter agreement).

Paul L. Feldman, PhD

We entered into a letter agreement with Dr. Feldman dated October 26, 2022, pursuant to which he agreed to serve as our Chief Scientific Officer. The letter agreement provided for at-will employment and either party had the ability to terminate his employment, at any time, for any reason or no reason.

The letter agreement provided that Dr. Feldman was entitled to an initial annualized base salary of $385,000 and also provided that Dr. Feldman was entitled to an annual discretionary bonus, with a target of 30% of his base salary. The base salary is reviewed annually, typically in connection with our annual performance review process and may be adjusted from time to time to realign salaries with market levels. Dr. Feldman was generally required to remain employed with us through the date of payment in order to earn a discretionary bonus for a fiscal year, but if, after the end of a fiscal year but prior to payment of the bonus for such fiscal year, we terminated his employment without cause (as defined in the letter agreement), he resigned for good reason (as defined in the letter agreement) or his employment terminated due to his death or disability (as defined in the letter agreement), he would be deemed to have earned the bonus for such prior year as if he had remained employed by us through the payment date.

Potential Payments Upon Termination of Employment or Change in Control

Prior to the closing of the IPO, each of our named executive officers was entitled to severance and other benefits upon a termination of his or her employment in certain circumstances, as described below. The terms “cause”, “good reason” and “change of control” referred to below were defined in the named executive officer’s employment agreement.

Matthew Roden, PhD

Dr. Roden's letter agreement provided that if we terminated Dr. Roden's employment without cause (as defined in the letter agreement), he resigned for good reason (as defined in the letter agreement) or his employment terminated due to his death or disability, then, subject to his timely execution and delivery of a separation agreement that included a general release of claims, he would be eligible to receive (i) payment of base salary for 12 months (or 18 months if the termination occurred within 12 months after a change of control (as defined in the letter agreement)), (ii) a prorated bonus for the year of termination, paid at the same time that bonuses are paid to other employees, (iii) payment of his COBRA premiums for the severance period described above (or if earlier, until he was no longer eligible for COBRA coverage or became eligible for comparable health insurance coverage in connection with new employment or self-employment), and (iv) accelerated vesting of equity awards for the number of shares that would have vested had he continued to provide service through the end of the severance period (provided that if the termination occurred within 12 months after a change of control, he was entitled to full acceleration of his outstanding equity awards).

Akos Czibere, MD, PhD

Dr. Czibere's letter agreement provided that if we terminated Dr. Czibere's employment without cause (as defined in the letter agreement), he resigned for good reason (as defined in the letter agreement) or his employment terminated due to his death or disability, then, subject to his timely execution and delivery of a separation agreement that included a general release of claims, he would be eligible to receive (i) payment of base salary for 6 months, (ii) payment of his COBRA premiums for the severance period described above (or, if earlier, until he was no longer eligible for COBRA coverage or became eligible for comparable health insurance coverage in connection with new employment or self-employment), and (iii) if the termination occurred within 12 months after a change of control (as defined in the letter agreement), he was entitled to full acceleration of his outstanding equity awards.

Paul L. Feldman, PhD

Dr. Feldman's letter agreement provided that if we terminated Dr. Feldman's employment without cause (as defined in the letter agreement), he resigned for good reason (as defined in the letter agreement) or his employment terminated due to his death or disability, then, subject to his timely execution and delivery of a separation agreement that included a general release of claims, he would be eligible to receive (i) payment of base salary for 6 months, (ii) payment of his COBRA premiums for the severance period described above (or, if earlier, until he was no longer eligible for COBRA coverage or became eligible for comparable health insurance coverage in connection with new employment or self-employment), and (iii) if the termination occurred within 12 months after a change of control (as defined in the letter agreement), he was entitled to full acceleration of his outstanding equity awards.

Employment Arrangements in Place as of the Closing of the IPO for Named Executive Officers

Effective as of the closing of the IPO, we entered into an employment agreement with each of our named executive officers, or an Executive Agreement. The Executive Agreements provide for each named executive officer's at-will employment and set forth, among other things, the applicable named executive officer's annual base salary and annual target cash bonus. Pursuant to his Executive Agreement, Dr. Roden's base salary was increased to $664,000, and he is eligible to receive an annual discretionary bonus with an annual target amount of 60% of his base salary. Pursuant to their respective Executive Agreements, Drs. Czibere's and Feldman's base salary was increased to $515,000 and $505,000, respectively, and each is eligible to receive an annual discretionary bonus with an annual target amount of their respective base salary. In addition, each named executive officer is eligible to participate in our benefit plans and programs, subject to the terms of such plans.

Each of the named executive officers will also be eligible to receive severance payments and benefits in connection with a termination without "cause" or for "good reason" (as defined in the Executive Agreements). In connection with such a termination, a named executive officer would be eligible to receive the following payments and benefits subject to the name executive officer's execution of a release and subject to not breaching any of the named executive officer's post-employment contractual obligations to us: (i) continued payment of the named executive officer's then-current base salary for a period of 9 months (12 months in the case of Dr. Roden) following termination, (ii) a pro-rated target bonus for the year in which the termination occurs, (iii) if the named executive officer was participating in the Company's group health plan immediately prior to the termination date and timely elects continuation coverage under COBRA, company-paid COBRA premiums for the named executive officer and such named executive officer's eligible dependents for a period of 9 months (12 months in the case of Dr. Roden) following termination and (iv) in the case of Dr. Roden, accelerated vesting of the unvested portion of any outstanding time-based equity award in an amount equal to the amount that would have vested had the named executive officer remained employed with us through the 12 months following the date of termination.

Each of the named executive officers will also be eligible to receive enhanced severance payments and benefits (in lieu of the payments and benefits described in the immediately preceding sentence) if such a qualifying termination of employment occurs within 12 months following a "change in control" (as defined in the Executive Agreements). In connection with such a termination, a named executive officer would be eligible to receive the following payments and benefits subject to the named executive officer's execution of a release and subject to not breaching any of the named executive officer's post-employment contractual obligations

to us: (i) a lump sum payment equal to 0.75x (or 1.0x in the case of Dr. Roden) the sum of the named executive officer's (A) then-current base salary, plus (B) the target bonus for the year of termination; (ii) the pro rated target bonus for the year of termination, (iii) if the named executive officer was participating in our group health plan immediately prior to the termination date and timely elects continuation coverage under COBRA, company-paid COBRA premiums for the named executive officer and the named executive officer's eligible dependents for a period of 9 months (or 12 months in the case of Dr. Roden) following termination, and (iii), in the case of Dr. Roden, 100% of all unvested and outstanding time-based equity awards shall accelerate and become fully vested and exercisable or nonforfeitable.

Employee and Retirement Benefits

We currently provide broad-based health and welfare benefits to our full-time employees, including our named executive officers, including health, life, disability, vision, and dental insurance. In addition, we maintain a safe-harbor 401(k) retirement plan under which we make discretionary matching non-elective contributions to eligible plan participants. We did not provide any matching or discretionary contributions under the 401(k) plan during the fiscal year ended December 31, 2025. Other than the 401(k) plan, we do not provide any qualified or non-qualified retirement or deferred compensation benefits to our employees, including our named executive officers.

Outstanding Equity Awards at Fiscal Year-End 2025

The following table sets forth information about the outstanding equity awards held by each of our named executive officers as of December 31, 2025:

	Option awards			
Name	**Number of securities underlying unexercised options (#) exercisable**	**Number of securities underlying unexercised options (#) unexercisable**	**Option exercise price ($)**	**Option expiration date**
Matthew Roden, PhD	430,198	127,897	$ 3.66	11/15/2032
	578,277	—	$ 1.91	4/14/2031
	180,470	438,286	$ 9.33	10/10/2034
Akos Czibere, MD, PhD	28,750	69,820	$ 9.33	10/10/2034
	96,056	175,162	$ 4.95	06/30/2034
	—	19,714	$ 11.46	12/11/2035
Paul L. Feldman, PhD	91,920	27,328	$ 3.66	11/15/2032
	65,713	—	$ 1.91	4/14/2031
	26,449	64,234	$ 9.33	10/10/2034

Non-Employee Director Compensation

The following table sets forth the compensation paid to, received by, or earned during fiscal year 2025 by the non-employee directors of our Board.

Name	**Fees earned or paid in cash ($)**	**All other compensation ($)**	**Total ($)**
Todd Foley, MBA[1]	—	—	—
Ken Herrmann, MD[2]	$ 45,000	$ 25,000	$ 70,000
Helen S. Kim, MBA[1]	—	—	—
Andrew Levin, MD, PhD[1][3]	—	—	—
Oleg Nodelman[1]	—	—	—
Lloyd M. Segal, MBA[4]	$ 45,000	—	$ 45,000
Mary Thistle[5]	$ 45,000	—	$ 45,000
Mike Sherman, MBA[5]	$ 18,750	—	$ 18,750

(1) As of December 31, 2025, Mr. Foley, Ms. Kim, Dr. Levin and Mr. Nodelman did not hold any outstanding options or any unvested stock awards.
(2) As of December 31, 2025, Dr. Herrmann held outstanding options to purchase an aggregate of 127,483 shares of our common stock, and did not hold any other unvested stock awards. The amount reflected in "All other compensation" is the payment received for services Dr. Herrmann provided as the chair of our scientific advisory board during fiscal year 2025.

(3) Dr. Levin resigned from our board of directors effective immediately prior to the effectiveness of our registration statement on Form S-1.
(4) As of December 31, 2025, Mr. Segal held outstanding options to purchase an aggregate of 81,483 shares of our common stock, and did not hold any other unvested stock awards.
(5) As of December 31, 2025, Ms. Thistle and Mr. Sherman held outstanding options to purchase an aggregate of 74,913 shares of our common stock, and did not hold any other unvested stock awards.

In connection with the IPO, we adopted a non-employee director compensation policy, which became effective upon completion of the IPO. Under the policy, our non-employee directors are compensated as follows:

- each non-employee director will receive an annual cash retainer of $45,000 ($75,000 for the chair of our board of directors);
- each non-employee director who is a member of the audit committee will receive an additional annual cash retainer of $10,000 ($20,000 for the audit committee chair);
- each non-employee director who is a member of our compensation committee will receive an additional annual cash retainer of $7,500 ($15,000 for our compensation committee chair); and
- each non-employee director who is a member of the nominating and corporate governance committee will receive an additional annual cash retainer of $5,000 ($10,000 for the nominating and corporate governance committee chair).

We will reimburse our non-employee directors for reasonable out-of-pocket travel and other expenses incurred in connection with attending meetings of our board of directors and any committee of our board of directors on which they serve.

Under the policy, each non-employee director will receive, upon their initial election or appointment to our board of directors, an option to purchase 37,866 shares of our common stock under our 2026 Plan. One-third of each of these options will vest over three years in three equal annual installments, subject to the non-employee director's continued service as a director.

Further, under the policy, beginning on the date of each annual meeting of our stockholders occurring after the first annual meeting of our stockholders, each non-employee director will receive an option to purchase 18,933 shares of our common stock under our 2026 Plan. Each of these options will vest upon the earlier of the first anniversary of the date of grant or the next annual meeting of our stockholders, subject to the non-employee director's continued service as a director.

All options issued to our non-employee directors under our non-employee director compensation program will become exercisable in full upon specified change in control events.

Director IPO Option Grants

Our non-employee directors received an option under our 2026 Plan to purchase shares of our common stock in connection with the effectiveness of the IPO. Ken Herrmann, Lloyd M. Segal, Mary Thistle and Michael A. Sherman each received an option to purchase 18,933 shares of our common stock, with an exercise price of $18.00, which was equal to the initial price per share to the public in the IPO, and will vest in full upon the one year anniversary of the grant date, subject to each director's continued service as a director. Todd Foley, Oleg Nodelman and Helen S. Kim each received an option to purchase 37,866 shares of our common stock, with an exercise price of $18.00, which was equal to the initial price per share to the public in the IPO, and will vest in three years in thirty-six equal monthly installments, subject to each director's continued service as a director

Equity plans

2026 Equity Incentive Plan

Our 2026 Equity Incentive Plan, or 2026 Plan, became effective January 8, 2026 and serves as the successor to the 2020 Plan. The material terms of the 2026 Plan are summarized below. The purpose of the 2026 Plan is to provide incentives for our employees, directors and consultants to exert maximum efforts for the success of the Company and our affiliates and to provide a means by which such persons may be given an opportunity to benefit from increases in value of our common stock through the granting of awards. Upon the effectiveness of the 2026 Plan, no further grants may be made under the 2020 Equity Incentive Plan, or the 2020 Plan.

The 2026 Plan provides for the grant of incentive stock options, or ISOs, within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards and other forms of awards to our employees, directors and consultants and any of our affiliates' employees and consultants.

Authorized Shares. Initially, the maximum number of shares of our common stock that may be issued under the 2026 Plan will not exceed 4,009,452 shares of our common stock, consisting of any shares of our common stock subject to outstanding stock options or other stock awards granted under the 2020 Plan that, following the effective date of the 2026 Plan, terminate or expire prior to exercise or settlement; are not issued because the award is settled in cash; are forfeited because of the failure to vest; or are

reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. In addition, the number of shares of our common stock reserved for issuance under the 2026 Plan will automatically increase on January 1 of each year for a period of ten years, beginning on January 1, 2027 and continuing through January 1, 2036, in an amount equal to 5.0% of the total number of shares of our common stock, Class A common stock and any prefunded warrants outstanding on December 31st of the immediately preceding calendar year; provided, however, that our board of directors may act prior to January 1st of a given year to provide that the increase for such year will be a lesser number of shares of our common stock. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under the 2026 Plan is 12,028,356 shares.

Shares subject to awards granted under the 2026 Plan that expire or terminate without being exercised in full will not reduce the number of shares available for issuance under the 2026 Plan. The settlement of any portion of an award in cash will not reduce the number of shares available for issuance under the 2026 Plan. Shares withheld under an award to satisfy the exercise, strike or purchase price of an award or to satisfy a tax withholding obligation will not reduce the number of shares that will be available for issuance under the 2026 Plan. With respect to a stock appreciation right, only shares of our common stock that are issued upon settlement of the stock appreciation right will count towards reducing the number of shares available for issuance under the 2026 Plan. If any shares of our common stock issued pursuant to an award are forfeited back to or repurchased or reacquired by us (i) because of a failure to meet a contingency or condition required for the vesting of such shares; (ii) to satisfy the exercise, strike or purchase price of an award; or (iii) to satisfy a tax withholding obligation in connection with an award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under the 2026 Plan.

Plan Administration. Our board of directors, or a duly authorized committee of our board of directors, will administer the 2026 Plan. Our board of directors, or a duly authorized committee of our board of directors, may, in accordance with the terms of the 2026 Plan, delegate to one or more of our officers the authority to (i) designate employees (other than officers) to be recipients of specified awards, and to the extent permitted by applicable law, the terms of such; and (ii) determine the number of shares subject to such awards granted to such employees. Under the 2026 Plan, our board of directors, or a duly authorized committee of our board of directors, have the authority to determine award recipients, how and when each award will be granted; the types of awards to be granted, grant dates, the number of shares subject to each award, the fair market value of our common stock, and the provisions of each award, including the period of exercisability and the vesting schedule applicable to an award. Under the 2026 Plan, (i) our board of directors will not, without stockholder approval, (A) reduce the exercise or strike price of an option or stock appreciation right (other than in connection with a capitalization adjustment), and (B) at any time when the exercise or strike price of an option or stock appreciation right is above the fair market value of a share of our common stock, cancel and re-grant or exchange such option or stock appreciation right for a new award with a lower (or no) purchase price or for cash, and (ii) a participant's rights under any award will not be materially adversely affected without the participant's written consent.

We have also designated a plan administrator to administer the day-to-day operations of the 2026 Plan.

Stock Options. ISOs and NSOs will be granted under stock option agreements adopted by the plan administrator. The plan administrator will determine the exercise price for stock options, within the terms and conditions of the 2026 Plan, except the exercise price of a stock option generally will not be less than 100% (or 110% in the case of ISOs granted to a person who owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations, or a ten percent stockholder) of the fair market value of our common stock on the date of grant. Options granted under the 2026 Plan will vest at the rate specified in the stock option agreement as will be determined by the plan administrator. The terms and conditions of separate options need not be identical.

No option will be exercisable after the expiration of ten years (or five years in the case of ISOs granted to a ten percent stockholder) or a shorter period specified in the applicable award agreement. Unless the terms of an optionholder's stock option agreement, or other written agreement between us and the recipient, provide otherwise, if an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death, or cause, the optionholder may generally exercise any vested options for a period of 90 days following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. If a participant is suspended pending investigation of whether his or her service relationship with us or any of our affiliates shall be terminated for cause, the participant's rights to exercise an option will be suspended during the investigation period. An optionholder may not exercise an option at any time that the issuance of shares upon such exercise would violate applicable law. Unless provided otherwise in the optionholder's stock option agreement or other written agreement between an optionholder and us, if an optionholder's service relationship with us or any of our affiliates ceases for any reason other than for cause and, at any time during the last thirty days of the applicable post-termination exercise period: (i) the exercise of the optionholder's option would be prohibited solely because the issuance of shares upon such exercise would violate applicable law, (ii) the immediate sale of any shares issued upon such exercise would violate our trading policy or (iii) our board of directors has

suspended exercisability of such optionholder's option pending investigation of whether his or her service relationship with us or any of our affiliates shall be terminated for cause, then the applicable post-termination exercise period will be extended to the last day of the calendar month that begins after the date the award would otherwise expire, with an additional extension of the exercise period to the last day of the next calendar month to apply if any of the foregoing restrictions apply at any time during such extended exercise period. There is no limitation as to the maximum permitted number of extensions. However, in no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (i) cash, check, bank draft or money order payable to us; (ii) a broker-assisted cashless exercise; (iii) subject to certain conditions, the tender of shares of our common stock previously owned by the optionholder; (iv) a net exercise of the option if it is an NSO; or (v) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options or stock appreciation rights generally will not be transferable except by will or the laws of descent and distribution. Subject to approval of the plan administrator or a duly authorized officer, an option may be transferred pursuant to a domestic relations order.

Tax Limitations on ISOs. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by any participant during any calendar year under all of our stock plans or plans of our affiliates may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, is a ten percent stockholder unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Unit Awards. Subject to the terms of the 2026 Plan, each restricted stock unit award will have such terms and conditions as determined by the plan administrator. A restricted stock unit award represents a participant's right to be issued on a future date the number of shares of our common stock that is equal to the number of restricted stock units subject to the award. A participant will not have voting or any other rights as a stockholder of ours with respect to any restricted stock unit award (unless and until shares are actually issued in settlement of a vested restricted stock unit award). A restricted stock unit award will generally be granted in consideration for a participant's services to us or an affiliate, such that the participant will not be required to make any payment to us (other than such services) with respect to the grant or vesting of the restricted stock unit award, or the issuance of any shares pursuant to the restricted stock unit award. If, at the time of grant, our board of directors determines that a participant must pay consideration upon the issuance of shares pursuant to a restricted stock unit award, such consideration may be paid in any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock (or any combination of our common stock and cash), or in any other form of consideration determined by our board of directors and set forth in the restricted stock unit award agreement. At the time of grant, the plan administrator may impose such restrictions or conditions on the award of restricted stock units that delay delivery to a date following the vesting of the award in a manner intended to comply with Section 409A of the Code, as applicable. Additionally, dividends or dividend equivalents may be paid or credited in respect of shares covered by a restricted stock unit award, subject to the same restrictions on transferability and forfeitability as the underlying award with respect to which such dividends or dividend equivalents are granted and subject to such other terms and conditions as determined by the plan administrator and specified in the applicable restricted stock unit award agreement. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the recipient, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

Restricted Stock Awards. Restricted stock awards will be granted under restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past or future services to us or any of our affiliates, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The plan administrator will determine the terms and conditions of restricted stock awards, including vesting and forfeiture terms. Dividends or dividend equivalents may be paid or credited with respect to shares subject to a restricted stock award, subject to the same restrictions on transferability and forfeitability as the underlying award with respect to which such dividends or dividend equivalents are granted and subject to such other terms and conditions as determined by the plan administrator and specified in the applicable restricted stock award agreement. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of our common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

Stock Appreciation Rights. Stock appreciation rights will be granted under stock appreciation right agreements adopted by the plan administrator and denominated in shares of common stock equivalents. The terms of separation stock appreciation rights need not be identical. The plan administrator will determine the purchase price or strike price for a stock appreciation right, which generally will not be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2026 Plan will vest at the rate specified in the stock appreciation right agreement as will be determined by the plan administrator. Stock appreciation rights may be settled in cash or shares of our common stock (or any combination of our

common stock and cash) or in any other form of payment, as determined by our board of directors and specified in the stock appreciation right agreement.

The plan administrator will determine the term of stock appreciation rights granted under the 2026 Plan, up to a maximum of 10 years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability, or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us or any of our affiliates ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation rights for a period of 18 months following the date of death. If a participant's service relationship with us or any of our affiliates ceases due to disability, the participant may generally exercise any vested stock appreciation rights for a period of 12 months following the cessation of service. In the event of a termination for cause, stock appreciation rights generally terminate upon the termination date. If a participant is suspended pending investigation of whether his or her service relationship with us or any of our affiliates shall be terminated for cause, the participant's rights to exercise a stock appreciation right will be suspended during the investigation period. A holder of a stock appreciation right may not exercise a stock appreciation right at any time that the issuance of shares upon such exercise would violate applicable law. Unless provided otherwise in the stock appreciation right agreement or other written agreement between the participant and us, if a participant's service relationship with us or any of our affiliates ceases for any reason other than for cause and, at any time during the last thirty days of the applicable post-termination exercise period: (i) the exercise of the participant's stock appreciation right would be prohibited solely because the issuance of shares upon such exercise would violate applicable law, (ii) the immediate sale of any shares issued upon such exercise would violate our trading policy or (iii) our board of directors has suspended exercisability of such optionholder's option pending investigation of whether his or her service relationship with us or any of our affiliates shall be terminated for cause, then the applicable post-termination exercise period will be extended to the last day of the calendar month that begins after the date the award would otherwise expire, with an additional extension of the exercise period to the last day of the next calendar month to apply if any of the foregoing restrictions apply at any time during such extended exercise period. There is no limitation as to the maximum permitted number of extensions. However, in no event may a stock appreciation right be exercised beyond the expiration of its term.

Other Stock Awards. The plan administrator is permitted to grant other awards, based in whole or in part by reference to, or otherwise based on, our common stock, either alone or in addition to other awards. The plan administrator has the sole and complete discretion to determine the persons to whom and the time or times at which other stock awards will be granted, the number of shares under the other stock award (or cash equivalent) and all other terms and conditions of such awards.

Non-Employee Director Compensation Limit. The aggregate value of all compensation granted or paid following the effective date of the 2026 Plan to any individual for service as a non-employee director with respect to any fiscal year, including awards granted under the 2026 Plan (valued based on the grant date fair value for financial reporting purposes) and cash fees paid by us to such non-employee director, will not exceed $750,000 in total value, except such amount will increase to $1,000,000 for the year in which a non-employee director is first appointed or elected to our board of directors.

Changes to Capital Structure. In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, our board of directors will appropriately and proportionately adjust (i) the class and maximum number of shares subject to the 2026 Plan; (ii) the class and maximum number of shares that may be issued on the exercise of ISOs; and (iii) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding awards granted under the 2026 Plan.

Corporate Transactions. In the event of a corporate transaction (as defined below), unless otherwise provided in a participant's award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the plan administrator at the time of grant, any awards outstanding under the 2026 Plan may be assumed, continued or substituted for, in whole or in part, by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to our common stock issued pursuant to awards may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such awards, then (i) with respect to any such awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such awards will be accelerated in full (or, in the case of awards with performance-based vesting with multiple vesting levels depending on the level of performance, unless provided otherwise in the applicable award agreement, vesting will accelerate at 100% of the target level) to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such awards will lapse (contingent upon the effectiveness of the corporate transaction); and (ii) any such awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the occurrence of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event an award will terminate if not exercised prior to the effective time of a corporate transaction, the plan administrator may provide, in its sole discretion, that the holder of such award may not exercise such award but instead will receive a payment, in such form as may be determined by our board of directors, equal in value to the excess (if any) of (i) the value of the property the participant would have received upon the exercise of the award, over (ii) any per share exercise price payable by such holder, if applicable. As a condition to the receipt of an award, a participant will be deemed to have agreed that the award will be subject to the terms of any agreement under the 2026 Plan governing a corporate transaction involving us.

Under the 2026 Plan, a "corporate transaction" generally is the consummation, in a single transaction or in a series of related transactions, of (i) a sale or other disposition of all or substantially all, as determined by our board of directors, of our consolidated assets; (ii) a sale or other disposition of at least 50% of our outstanding securities; (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation; or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change in Control. Awards to be granted under the 2026 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control (as defined below) as may be provided in the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

Under the 2026 Plan, a "change in control" generally is: (i) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (ii) a merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity) in substantially the same proportions as their ownership immediately prior to such transaction; (iii) stockholder approval of a complete dissolution or liquidation; (iv) a sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of our outstanding voting securities immediately prior to such transaction; or (v) when a majority of our board of directors becomes comprised of individuals who were not serving on our board of directors on the date of the underwriting agreement related to this offering, or the incumbent board, or whose nomination, appointment, or election was not approved by a majority of the incumbent board still in office.

Transferability. Except as expressly provided in the 2026 Plan or the form of award agreement, awards granted under the 2026 Plan may not be transferred or assigned by a participant. After the vested shares subject to an award have been issued, or in the case of a restricted stock award and similar awards, after the issued shares have vested, the holder of such shares is free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such shares provided that any such actions are in compliance with the provisions herein, the terms of our trading policy and applicable law.

Clawback/Recovery. All awards granted under the 2026 Plan are subject to recoupment in accordance with the clawback policy that we have adopted. In addition, our board of directors may impose such other clawback, recovery or recoupment provisions in an award agreement as our board of directors determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of our common stock or other cash or property upon the occurrence of cause.

Amendment or Termination. Our board of directors may accelerate the time at which an award granted under the 2026 Plan may first be exercised or the time during which an award grant under the 2026 Plan or any part thereof will vest, notwithstanding the provisions in the award agreement stating the time at which it may first be exercised or the time during which it will vest. Our board of directors will have the authority to amend, suspend, or terminate the 2026 Plan at any time, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments will also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopts the 2026 Plan. No awards may be granted under the 2026 Plan while it is suspended or after it is terminated.

We filed a registration statement on Form S-8 with the SEC on January 12, 2026 to register all of the shares of our common stock reserved for issuance under the 2026 Plan.

2020 Equity incentive plan

In 2020, our board of directors adopted and our stockholders initially approved the 2020 Plan. No further awards will be made under the 2020 Plan following the completion of our IPO in January 2026; however, awards outstanding under the 2020 Plan will continue to be governed by their existing terms.

Share Reserve. As of December 31, 2025, we had reserved 6,185,598 shares of our common stock for issuance under the 2020 Plan. As of December 31, 2025, options to purchase 5,899,875 shares of our common stock, at exercise prices ranging from $0.08 to $11.45 per share, or a weighted-average exercise price of $5.87 per share were outstanding under the 2020 Plan, and 285,723 shares of our common stock remained available for future issuance under the 2020 Plan. Unissued shares subject to awards that expire or terminate for any reason without being exercised in full, or shares issued pursuant to the 2020 Plan that are reacquired

by us at no more than the price at which the shares were previously issued will again become available for issuance under the 2026 Plan.

Administration. Our board of directors, or a committee thereof, administered the 2020 Plan from its adoption until the closing of the IPO. Following the closing of the IPO, the compensation committee of our board of directors administers the 2020 Plan. The administrator has complete discretion to make all decisions relating to the 2020 Plan and outstanding awards.

Eligibility. Employees, non-employees and directors of ours or our affiliates, as well as any other person who our board of directors determines to have made (or is expected to make) contributions to us are eligible to participate in the 2020 Plan. However, only employees are eligible to receive incentive stock options.

Types of Awards. The 2020 Plan provided for the following types of awards granted with respect to shares of our common stock:

- ISOs and NSOs to purchase shares of our common stock;
- restricted stock awards; and
- other stock-based awards.

Options. The exercise price for options granted under the 2020 Plan is determined by our board of directors, but may not be less than 100% of the fair market value of our common stock on the grant date (or 110% in the case of ISOs granted to a ten percent stockholder). Optionees may pay the exercise price in cash or cash equivalents or by one, or any combination of, the following forms of payment, as permitted by the administrator in its sole discretion:

- by check payable to the order of the Company;
- to the extent provided in an award agreement, delivery of shares of our common stock that the optionee already owns;
- delivery of a full-recourse promissory note;
- through a broker-assisted sale of the option shares pursuant to which a creditworthy broker will deliver sufficient funds to the Company to pay the exercise price, if the shares of our common stock are publicly traded; or
- other lawful consideration as our board of directors may determine.

Options vest as determined by the administrator. In general, we have granted options that vest over a four-year period. Options expire at the time determined by the administrator, but in no event more than ten years after they are granted (or five years after the grant date for ISOs granted to ten percent stockholders), and generally expire earlier if the optionee's service terminates.

Restricted Shares. Restricted shares were awarded or sold under the 2020 Plan in return for cash or a check for at least the par value of the shares, delivery of a promissory note or any other form of consideration acceptable to the administrator in its sole discretion, in exchange for services rendered to us, by delivery of a full-recourse promissory note or through any other means permitted by applicable law. Restricted shares vest as determined by the administrator.

Other Stock-Based Awards. The administrator could grant other awards based on our common stock having such terms and conditions that it may determine, including stock appreciation rights, phantom stock awards or stock units.

Change of Control. In the event of a change of control (as defined in the 2020 Plan to include the acquisition 50% or more of our voting stock other than pursuant to an equity financing, a reorganization, merger or consolidation, a sale of all or substantially all of our stock or assets, or a liquidation or dissolution), unless otherwise provided in an award agreement, our board of directors, in its discretion, will take one or more of the following actions with respect to awards granted under the 2020 Plan:

- the continuation or assumption of an award by the surviving or acquiring entity;
- accelerate the vesting of an award;
- permit the exchange of any award for the right to participate in any stock option or benefit plan of a successor corporation;
- provide for the repurchase of an award in exchange for an amount equal to the excess, if any, of the consideration received for a share underlying the award in the change of control over any exercise price per share applicable to the award; or
- provide for the termination of the award immediately prior to the change of control.

The administrator is not obligated to treat all awards in the same manner. The administrator has the discretion, at any time, to provide that an award under the 2020 Plan will vest on an accelerated basis in connection with a corporate transaction or to amend or modify an award so long as such amendment or modification is not inconsistent with the terms of the 2020 Plan or would not result in the impairment of a participant's rights without the participant's consent.

Changes in Capitalization. In the event of certain specified changes in the capital structure of our common stock, such as a stock split, reverse stock split, stock dividend, extraordinary cash dividend, recapitalization, reorganization, merger, consolidation, combination, exchange of shares, liquidation, spin-off, split-up, or other similar change in capitalization or similar event, proportionate adjustments will automatically be made in (i) the number and class of shares, as well as the vesting schedule and exercise price per share subject to each outstanding option, (ii) any repurchase price applicable to shares granted under the 2020 Plan and (iii) any other terms of outstanding awards as determined by the administrator to be appropriate.

Amendments or Termination. Our 2020 Plan terminated on the date that our 2026 Plan became effective. Awards outstanding under the 2020 Plan will remain outstanding and will continue to be governed by their existing terms.

We filed a registration statement on Form S-8 with the SEC on January 12, 2026 to register all of the shares of our common stock reserved for issuance under the 2026 Plan.

2026 Employee Stock Purchase Plan

In order to incentivize our employees, our board of directors and stockholders have adopted the 2026 Employee Stock Purchase Plan, or the ESPP, which became effective on January 8, 2026. The material terms of the ESPP are summarized below.

Purpose. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our related corporations. The ESPP includes two components. One component is designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code, or the 423 Component, and accordingly, it is construed in a manner that is consistent with the requirements of Section 423 of the Code. We intend (but make no undertaking or representation to maintain) the 423 Component to qualify as an employee stock purchase plan, as that term is defined in Section 423(b) of the Code. The other component permits the grant of purchase rights that do not qualify for such favorable tax treatment, or the Non-423 Component, in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws, and except as otherwise provided in the ESPP or determined by our board of directors, it operates and is administered in the same manner as the 423 Component.

Share Reserve. Initially, the maximum number of shares of our common stock that may be issued under the ESPP will not exceed 27,843 shares of our common stock. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each year for a period of ten years, beginning on January 1, 2027 and ending on (and continuing through) January 1, 2036, in an amount equal to 1.0% of the total number of shares of our common stock, Class A common stock and any prefunded warrants outstanding on December 31st of the immediately preceding calendar year; provided, however, that our compensation committee may act prior to January 1 of a given year to provide that there will be no increase for such calendar year or the increase for such year will be a lesser number of shares than the amount set forth above. For the avoidance of doubt, up to the maximum number of shares of our common stock reserved may be used to satisfy purchases of our common stock under the 423 Component and any remaining portion of such maximum number of shares may be used to satisfy the purchases of our common stock under the Non-423 Component.

If any purchase right granted under the ESPP terminates without having been exercised in full, the shares of our common stock not purchased under such purchase right will again become available for issuance under the ESPP.

The common stock purchasable under the ESPP will be shares of authorized but unissued or reacquired common stock, including shares repurchased by us on the open market.

Administration. Our board of directors administers the ESPP. Our board of directors may delegate some or all of the administration of the ESPP to a committee or committees of our board of directors. All references to our board of directors in this summary shall include a duly authorized committee of our board of directors except where the context dictates otherwise. Further, to the extent not prohibited by applicable law, our board of directors may, from time to time, delegate some or all of its authority under the ESPP to one or more of our officers or other persons or groups of persons as it deems necessary, appropriate or advisable under conditions or limitations that it may set at or after the time of the delegation. Our board of directors will have the authority to determine how and when purchase rights are granted and the provisions of each offering; to designate, from time to time, which of our related corporations will be eligible to participate in the 423 Component or the Non-423 Component, or which related corporations will be eligible to participate in each separate offering; to construe and interpret the ESPP and purchase rights thereunder, and to establish, amend and revoke rules and regulations for the ESPP's administration; to settle all controversies regarding the ESPP and purchase rights granted thereunder; to amend, suspend or terminate the ESPP; to exercise such powers and to perform such acts as it deems necessary or expedient to promote the best interests of us and our related corporations and to carry out the intent of the ESPP to be treated as an employee stock purchase plan with respect to the 423 Component; and to adopt such rules, procedures and sub-plans as are necessary or appropriate to permit or facilitate participation in the ESPP by employees who are foreign nationals or employed or located outside the United States.

All determinations, interpretations and constructions made by our board of directors in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

Offerings. Our board of directors may grant or provide for the grant of purchase rights to eligible employees under an offering (consisting of one or more purchase periods) on an offering date or offering dates selected by our board of directors. Each offering will be in the form and will contain those terms and conditions as our board of directors deems appropriate, and, with respect to the 423 Component, will comply with the requirements of Section 423(b)(5) of the Code. The provisions of separate offerings do not need to be identical, but each offering will include the period during which the offering will be effective, which period will not exceed 27 months beginning with the offering date, and the substance of the applicable provisions contained in the ESPP.

If a participant has more than one purchase right outstanding under the ESPP, unless he or she otherwise indicates in forms delivered to us or a third party designee of ours: (i) each form will apply to all of his or her purchase rights under the ESPP, and (ii) a purchase right with a lower exercise price (or an earlier-granted purchase right, if different purchase rights have identical exercise prices) will be exercised to the fullest possible extent before a purchase right with a higher exercise price (or a later-granted purchase right if different purchase rights have identical exercise prices) will be exercised.

Our board of directors will have the discretion to structure an offering so that if the fair market value of a share of our common stock on the first trading day of a new purchase period within that offering is less than or equal to the fair market value of a share of our common stock on the first day of that offering, then (i) that offering will terminate immediately as of that first trading day, and (ii) the participants in such terminated offering will be automatically enrolled in a new offering beginning on the first trading day of such new purchase period.

Eligibility. Generally, purchase rights may only be granted to employees, including executive officers, employed by us (or by any of our affiliates or related corporations as designated by our board of directors) on the first day of an offering if such employee has been employed by us or by one of our designated affiliates or related corporations for such continuous period preceding such date as our board of directors may require, but in no event will the required period of continuous employment be equal to or greater than two years with respect to the 423 Component. Our board of directors may (unless prohibited by applicable law) require that employees have to satisfy one or both of the following service requirements with respect to the 423 Component: (i) being customarily employed by us, or any of our related corporations or affiliates, for more than 20 hours per week and more than five months per calendar year; or (ii) such other criteria as our board of directors may determine consistent with Section 423 of the Code with respect to the 423 Component. Our board of directors may provide that each person who, during the course of an offering, first becomes an eligible employee will, on the date or dates specified in the offering which coincides with the day on which the person becomes an eligible employee or which occurs thereafter, receive a purchase right under that offering, and the purchase right will thereafter be deemed to be part of the offering with substantially identical characteristics. With respect to the 423 Component, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee owns stock possessing five percent or more of the total combined voting power or value of all classes of our outstanding capital stock (or the stock of any related corporation) determined in accordance with the rules of Section 424(d) of the Code. With respect to the 423 Component, as specified by Section 423(b)(8) of the Code, an employee may be granted purchase rights only if such purchase rights, together with any other rights granted under all employee stock purchase plans of ours or any of our related corporations, do not permit such employee's rights to purchase our stock or the stock of any of our related corporations to accrue at a rate which, when aggregated, exceeds $25,000 (based on the fair market value per share of such common stock on the date that the purchase right is granted) for each calendar year such purchase rights are outstanding at any time. Our board of directors may also exclude from participation in the ESPP or any offering employees of ours, or of any of our related corporation, who are highly compensated employees, as within the meaning of Section 423(b)(4)(D) of the Code, or a subset of such highly compensated employees.

Notwithstanding anything in the foregoing paragraph to the contrary, in the case of an offering under the Non-423 Component, an employee (or a group of employees) may be excluded from participation in the ESPP or an offering if our board of directors has determined, in its sole discretion, that participation of such employee is not advisable or practical for any reason.

Purchase Rights; Purchase Price. On the first day of each offering, each eligible employee, pursuant to an offering made under the ESPP, will be granted a purchase right to purchase up to that number of shares purchasable either with a percentage or with a maximum dollar amount, as designated by our board of directors, which will not exceed 15% of such employee's earnings (as defined by our board of directors) during each period that begins on the first day of the offering (or such later date as our board of directors determines for a particular offering) and ends on the date stated in the offering, which date will be no later than the end of the offering. Our board of directors will establish one or more purchase dates during an offering on which purchase rights granted for that offering will be exercised and shares of our common stock will be purchased in accordance with such offering. Each eligible employee may purchase of up to $25,000 of shares of our common stock in an offering (or such lesser number of shares determined by our board of directors prior to the start of the offering). Our board of directors may also specify (i) a maximum number of shares that may be purchased by any participant on any purchase date during an offering, (ii) a maximum aggregate number of shares that may be purchased by all participants in an offering and/or (iii) a maximum aggregate number of shares that may be purchased by all participants on any purchase date under an offering. If the aggregate number of shares issuable upon exercise of purchase rights

granted under the offering would exceed any such maximum aggregate number, then, in the absence of any action by our board of directors otherwise, a pro rata allocation of the shares (rounded down to the nearest whole share) available, based on each participant's accumulated contributions, will be made in as nearly a uniform manner as will be practicable and equitable.

The purchase price of shares acquired pursuant to purchase rights will not be less than the lesser of (i) 85% of the fair market value of a share of our common stock on the first day of an offering; or (ii) 85% of the fair market value of a share of our common stock on the date of purchase.

Participation; Withdrawal; Termination. An eligible employee may elect to participate in an offering and authorize payroll deductions as the means of making contributions by completing and delivering to us or our designee, within the time specified in the offering, an enrollment form provided by us or our designee. The enrollment form will specify the amount of contributions not to exceed the maximum amount specified by our board of directors, but in any event not to exceed 15% of the eligible employee's base wages. Each participant's contributions will be credited to a bookkeeping account for the participant under the ESPP and will be deposited with our general funds except where applicable law requires that contributions be deposited with a third party. If permitted in the offering, a participant may begin such contributions with the first payroll occurring on or after the first day of the applicable offering (or, in the case of a payroll date that occurs after the end of the prior offering but before the first day of the next new offering, contributions from such payroll will be included in the new offering). If permitted in the offering, a participant may thereafter reduce (including to zero) or increase his or her contributions. If required under applicable law or if specifically provided in the offering, in addition to or instead of making contributions by payroll deductions, a participant may make contributions through payment by cash, check or wire transfer prior to a purchase date.

During an offering, a participant may cease making contributions and withdraw from the offering by delivering to us or our designee a withdrawal form provided by us. We may impose a deadline before a purchase date for withdrawing. Upon such withdrawal, such participant's purchase right in that offering will immediately terminate and we will distribute as soon as practicable to such participant all of his or her accumulated but unused contributions and such participant's purchase right in that offering shall then terminate. A participant's withdrawal from that offering will have no effect upon his or her eligibility to participate in any other offerings under the ESPP, but such participant will be required to deliver a new enrollment form to participate in subsequent offerings.

Unless otherwise required by applicable law, purchase rights granted pursuant to any offering under the ESPP will terminate immediately if the participant either (i) is no longer an employee for any reason or for no reason (subject to any post-employment participation period required by applicable law) or (ii) is otherwise no longer eligible to participate. We will distribute the individual's accumulated but unused contributions as soon as practicable to such individual.

Unless otherwise determined by our board of directors, a participant whose employment transfers or whose employment terminates with an immediate rehire (with no break in service) by or between us and one of our designated companies designated to participate in an offering (or between such designated companies) will not be treated as having terminated employment for purposes of participating in the ESPP or an offering. However, if a participant transfers from an offering under the 423 Component to an offering under the Non-423 Component, the exercise of the participant's purchase right will be qualified under the 423 Component only to the extent such exercise complies with Section 423 of the Code. If a participant transfers from an offering under the Non-423 Component to an Offering under the 423 Component, the exercise of the purchase right will remain non-qualified under the Non-423 Component. Our board of directors may establish different and additional rules governing transfers between separate offerings within the 423 Component and between offerings under the 423 Component and offerings under the Non-423 Component. Unless otherwise specified in the offering or as required by applicable law, we will have no obligation to pay interest on contributions.

Purchase of Shares. On each purchase date, each participant's accumulated contributions will be applied to the purchase of shares, up to the maximum number of shares permitted by the ESPP and the applicable offering, at the purchase price specified in the offering. Unless otherwise provided in the offering, if any amount of accumulated contributions remains in a participant's account after the purchase of shares on the final purchase date of an offering, then such remaining amount will not roll over to the next offering and will instead be distributed in full to such participant after the final purchase date of such offering without interest (unless otherwise required by applicable law). No purchase rights may be exercised to any extent unless the shares of our common stock to be issued upon such exercise under the ESPP are covered by an effective registration statement pursuant to the Securities Act of 1933, as amended, or the Securities Act, and the ESPP is in material compliance with all applicable U.S. federal and state, foreign and other securities, exchange control and other laws applicable to the ESPP. If on a purchase date the shares of our common stock are not so registered or the ESPP is not in such compliance, no purchase rights will be exercised on such purchase date, and the purchase date will be delayed until the shares of our common stock are subject to such an effective registration statement and the ESPP is in material compliance, except that the purchase date will in no event be more than 27 months from the first day of an offering. If, on the purchase date, as delayed to the maximum extent permissible, the shares of our common stock are not registered and the ESPP is not in material compliance with all applicable laws, as determined by us in our sole discretion, no purchase rights will be exercised and all accumulated but unused contributions will be distributed to the ESPP participants without interest (unless the payment of interest is otherwise required by applicable law).

A participant will not be deemed to be the holder of, or to have any of the rights of a holder with respect to, shares of our common stock subject to purchase rights unless and until the participant's shares of our common stock acquired upon exercise of purchase rights are recorded in our books (or the books of our transfer agent).

Changes to Capital Structure. The ESPP provides that in the event of a change in our capital structure through actions such as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, our board of directors will appropriately and proportionately adjust: (i) the class(es) and maximum number of shares subject to the ESPP; (ii) the class(es) and maximum number of shares by which the share reserve is to increase automatically each year; (iii) the class(es) and number of shares subject to, and purchase price applicable to,

outstanding offerings and purchase rights; and (iv) the class(es) and number of shares that are subject to purchase limits under each ongoing offering. Our board of directors will make these adjustments, and its determination will be final, binding and conclusive.

Corporate Transactions. The ESPP provides that in the event of a corporate transaction (as defined below), any then-outstanding rights to purchase our common stock under the ESPP may be assumed, continued, or substituted for by any surviving or acquiring corporation (or its parent company). If the surviving or acquiring corporation (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then (i) the participants' accumulated payroll contributions will be used to purchase shares of our common stock (rounded down to the nearest whole share) within 10 business days (or such other period specified by our board of directors) before such corporate transaction under the outstanding purchase rights, and such purchase rights will terminate immediately after such purchase, or (ii) our board of directors, in its discretion, may terminate outstanding offerings, cancel the outstanding purchase rights and refund the participants' accumulated contributions.

Under the ESPP, a "corporate transaction" is generally the consummation, in a single transaction or in a series of related transactions, of: (i) a sale or other disposition of all or substantially all, as determined by our board of directors, of the consolidated assets of us and our subsidiaries; (ii) a sale or other disposition of at least 50% of our outstanding securities; (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation; or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Transferability. During a participant's lifetime, purchase rights will be exercisable only by a participant. Purchase rights are not transferable by a participant, except by will, by the laws of descent and distribution, or, if permitted by us, by a beneficiary designation.

Tax Withholding. Each participant must make arrangements, satisfactory to us and any applicable related corporation, to enable us or our related corporation to fulfill any withholding obligation for taxes arising out of or in relation to a participant's participation in the ESPP. In our sole discretion and subject to applicable law, such withholding obligation may be satisfied in whole or in part by (i) withholding from the participant's salary or any other cash payment due to the participant from us or any related corporation; (ii) withholding from the proceeds of the sale of shares of our common stock acquired under the ESPP, either through a voluntary sale or a mandatory sale arranged by us; or (iii) any other method deemed acceptable by our board of directors. We will not be required to issue any shares of our common stock under the ESPP until such obligations are satisfied.

Amendment, Suspension or Termination. Our board of directors has the authority to amend, suspend or terminate the ESPP. Any benefits, privileges, entitlements and obligations under any outstanding purchase right granted before an amendment, suspension or termination of the ESPP will not be materially impaired by any such amendment, suspension or termination except (i) with the consent of the person to whom such purchase rights were granted, (ii) as necessary to facilitate compliance with any laws, listing requirements, or governmental regulations (including, without limitation, the provisions of Section 423 of the Code), or (iii) as necessary to obtain or maintain favorable tax, listing, or regulatory treatment. Except with respect to certain changes in our capital structure, stockholder approval is required for any amendment to the ESPP if such approval is required by applicable law or listing requirements. No purchase rights may be granted under the ESPP while it is suspended or after it is terminated.

We filed a registration statement on Form S-8 with the SEC on January 12, 2026 to register all of the shares of our common stock reserved for issuance under the 2026 Plan.

Other Compensation and Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, in each case on the same basis as all of our other employees. These employee benefit plans include medical, dental, vision, short- and long-term disability and life and accidental dismemberment insurance plans. We pay a portion of the premiums for the medical, dental, vision and life and accidental death and dismemberment insurance for all of our employees, including our named executive officers. In addition, we provide the opportunity to participate in a 401(k) plan to our employees, including each of our named executive officers, as discussed above.

Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

From time to time, we grant equity awards, including stock options, to our employees, including our named executive officers. Our typical practice is to grant employee stock options on the first business day of the month following the month in which the options are approved (or on the same day of approval if such approval is on the first business day of a month). We typically grant annual refresh employee option grants in the first quarter of each fiscal year, which refresh grants are typically approved at a regularly scheduled meeting of the Compensation Committee occurring in such quarter. In addition, non-employee directors receive automatic grants of initial and annual stock option awards, at the time of a director's initial appointment or election to the board and at the time of each annual meeting of our stockholders, respectively, pursuant to our non-employee director compensation policy, as further described under the heading, "Non-Employee Director Compensation". We do not otherwise maintain any written policies on the timing of awards of stock options, stock appreciation rights, or similar instruments with option-like features. The Compensation Committee considers whether there is any material nonpublic information, MNPI, about our company when determining the timing of stock option grants and it does not seek to time the award of stock options in relation to the Company's public disclosure of MNPI. We have not timed the release of MNPI for the purpose of affecting the value of executive compensation.

Compensation Recovery Policy

We have adopted a compensation recovery policy that became effective upon the closing of the IPO, that applies to our officers. Under the Sarbanes-Oxley Act of 2022, in the event of misconduct that results in a financial restatement that would have reduced a previously paid incentive amount, we can recoup those improper payments from our chief executive officer and chief financial officer. The SEC also recently adopted rules which direct national stock exchanges to require listed companies to implement policies intended to recoup bonuses paid to executives if the company is found to have misstated its financial results.

Limitations On Liability and Indemnification

Our amended and restated certificate of incorporation, or Restated Charter, which became effective immediately prior to the completion of the IPO, contains provisions that limit the liability of our current and former directors and officers for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors and officers of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors or officers, except liability for:

- any breach of the director's or officer's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- as a director, unlawful payments of dividends or unlawful stock repurchases or redemptions;
- as an officer, derivative claims brought on behalf of the corporation by a stockholder; or
- any transaction from which the director or officer derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our Restated Charter authorizes us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws, or Restated Bylaws, provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our Restated Bylaws also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding.

We believe that these Restated Charter and Restated Bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our Restated Charter and Restated Bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Compensation Committee Interlocks

None of the members of the compensation committee is currently, or has been at any time, one of our officers or employees. None of our executive officers currently serves, or has served during the last completed fiscal year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

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

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding beneficial ownership of our capital stock as of March 10, 2026:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- our named executive officers; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. Under these rules, beneficial ownership includes any shares of common stock as to which the individual or entity has sole or shared voting power or investment power. Percentage ownership of our common stock is based on 53,403,173 shares of common stock outstanding as of March 10, 2026. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options held by such person that are currently exercisable or will become exercisable within 60 days of March 10, 2026, are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. Unless noted otherwise, the address of all listed stockholders is c/o 17 Drydock Avenue, Suite 17-401, Boston, Massachusetts 02210.

Except as indicated by the footnotes below, we believe, based on information furnished to us, that each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of beneficial owner	Number of shares of voting common stock beneficially owned	Number of shares of Class A common stock beneficially owned	Percentage of shares beneficially owned
Greater than 5% stockholders			
Entities affiliated with MPM BioImpact LLC[(1)]	10,260,064	—	19.2%
Eli Lilly and Company[(2)]	6,344,114	—	11.9%
Entities affiliated with VV Manager II, LLC[(3)]	5,829,212	—	10.9%
Entities affiliated with EcoR1 Capital, LLC[(4)]	4,824,469	1,051,412	9.0%
Named Executive Officers and Directors			
Matthew Roden, PhD[(5)]	1,403,522	—	2.6%
Akos Czibere, MD, PhD[(6)]	163,325	—	*%
Paul L. Feldman, PhD[(7)]	429,374	—	*%
Todd Foley, MBA[(8)]	4,239,610	—	7.9%
Ken Herrmann, MD[(9)]	84,302	—	*%
Helen S. Kim, MBA[(10)]	5,833,419	—	10.9%
Oleg Nodelman[(11)]	4,828,676	1,051,412	9.0%
Lloyd M. Segal, MBA[(12)]	88,080	—	*%
Michael A. Sherman	—	—	—%
Mary Thistle [(13)]	23,410	—	*%
All current executive officers and directors as a group (13 persons)[(14)]	17,630,335	1,051,412	33.0%

* Represents beneficial ownership of less than one percent.

(1) Based on a Schedule 13D filed with the SEC on January 20, 2026. Consists of (i) 341,709 shares of common stock held by MPM Asset Management LLC, (ii) 3,950,528 shares of common stock held by MPM Asset Management Investors BV2018 LLC, or MPM BV2018, (iii) 206,964 shares of common stock held by MPM BioVentures 2018(B), L.P., or MPM 2018(B) (iv) 77,911 shares of common stock held by MPM BioVentures 2018, L.P., or MPM BioVentures 2018, (v) 847,080 shares of common stock held by MPM Oncology Innovations Fund, L.P., or MPM Oncology, and (vi) 4,835,872 shares of common stock held by Oncology Impact Private Investment Fund 2, L.P., or MPM Oncology Impact. MPM Asset Management LLC, MPM BV2018, MPM 2018(B), MPM BioVentures 2018, MPM Oncology and MPM Oncology Impact are collectively referred to as the MPM BioImpact Entities. Todd Foley, a member of our board of directors, Luke Evnin and Ansbert Gadicke are the Managing Directors of MPM BioVentures 2018 LLC, or BV2018 LLC. BV2018 LLC is the Managing Member of MPM BioVentures 2018 GP LLC, which is the General Partner of MPM BioVentures 2018 and MPM 2018 (B) and the Manager of MPM BV2018. Each of Dr. Evnin, Dr. Gadicke, and Mr. Foley shares power to vote, acquire, hold and dispose of the shares held by each of the BV2018 funds. MPM Oncology Innovations Fund GP LLC is the General Partner of MPM Oncology. Ansbert Gadicke and Luke Evnin are Managers of MPM Oncology Innovations Fund GP LLC and share the power to vote, acquire, hold and dispose of all shares owned by the fund along with designated agents. MPM Oncology Investments 2 LLC is the General Partner of MPM Oncology Impact. Ansbert Gadicke is the Managing Member of MPM Oncology Investments 2 LLC and has sole authority to designate agents. If agents are designated, he shares the power to vote, acquire, hold and dispose of all shares owned by MPM Oncology Impact with such designated agents. MPM Asset Management LLC is the Management Company of the BV2018 family of funds and the MPM Oncology Fund. Ansbert Gadicke is the Manager of MPM Asset Management LLC and has the primary decision-making power to vote, acquire, hold and dispose of all shares owned. MPM BioImpact LLC is the Management Company of MPM Oncology Impact. Each of the entities and individuals listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address of each of the MPM BioImpact Entities is 399 Boylston Street, Suite 1100, Boston, Massachusetts 02116.

(2) Based on a Schedule 13D filed with the SEC on January 15, 2026. Consists of 6,344,114 shares of common stock held directly by Eli Lilly and Company.

(3) Based on a Schedule 13D filed with the SEC on January 14, 2026. Consists of (i) 5,671,825 shares of common stock held by Vida Ventures II, LLC, or Vida II, and (ii) 157,387 shares of common stock held by Vida Ventures II-A, LLC, or Vida II-A. Vida II and Vida II-A are collectively referred to as the Vida Ventures Funds. VV Manager II, LLC, or VV Manager is the manager of the Vida Ventures Funds and may be deemed to have voting, investment and dispositive power with respect to the shares held by each of the Vida Ventures Funds. Arie Belldegrun, Fred Cohen, and Leonard Potter, the members of the management committee of VV Manager II, along with the other members of the investment committee, Rajul Jain, Joshua Kazam, and Helen S. Kim, a member of our board of directors, may be deemed to share voting and dispositive power over the shares held by the Vida Ventures Funds. The principal business address of the VV Manager II, LLC is 40 Broad Street, Suite 201, Boston, Massachusetts, 02109.

(4) Based on a Schedule 13D filed with the SEC on January 20, 2026. Consists of (i) 4,348,658 shares of common stock held by EcoR1 Capital Fund Qualified, L.P., or Qualified Fund, (ii) 965,190 shares of Class A common stock held by Qualified Fund, (iii) 347,305 shares of common stock held by EcoR1 Capital Fund, L.P., or Capital Fund, (iv) 86,222 shares of Class A common stock held by Capital Fund, and (v) 128,506 shares of common stock held by EcoR1 Venture Opportunity Fund, L.P., or Venture Fund. The Qualified Fund, the Capital Fund and the Venture Fund are collectively referred to as the EcoR1 Capital Funds. The EcoR1 Capital Funds are managed by EcoR1 Capital, LLC, which is managed by Oleg Nodelman, a member of our board of directors, and as a result may be deemed to have voting and dispositive power over the securities held by these funds. The business address of EcoR1 Capital, LLC is 357 Tehama Street, #3, San Francisco, California 94103.

(5) Consists of (i) 91,998 shares of common stock and (ii) 1,311,534 shares of common stock underlying outstanding stock options exercisable within 60 days of March 10, 2026.

(6) Consists of 163,325 shares of common stock underlying outstanding stock options exercisable within 60 days of March 10, 2026.

(7) Consists of (i) 144,568 shares of common stock and (ii) 284,806 shares of common stock underlying outstanding stock options exercisable within 60 days of March 10, 2026.

(8) Consists of (i) 4,235,403 shares of common stock held by BV2018LLC and (ii) 4,207 shares of common stock underlying outstanding stock options exercisable within 60 days of March 10, 2026. Todd Foley is a Managing Director of BV2018 LLC. BV2018 LLC is the Managing Member of MPM BioVentures 2018 GP LLC, which is the General Partner of MPM BioVentures 2018, L.P., and MPM BioVentures 2018(B), L.P. and the Manager of MPM Asset Management Investors BV2018 LLC, collectively the BV2018 funds. Mr. Foley shares power to vote, acquire, hold and dispose of the shares held by each of the BV2018 funds with the other Managing Directors of BV2018, Dr. Luke Evnin, Dr. Ansbert Gadicke. Each of the individuals listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address of each of the BV2018 funds is 399 Boylston Street, Suite 1100, Boston, Massachusetts 02116.

(9) Consists of 84,302 shares of common stock underlying outstanding stock options exercisable within 60 days of March 10, 2026.

(10) Consists of (i) 5,829,212 shares of common stock held by the Vida Ventures Funds and (ii) 4,207 shares of common stock underlying outstanding stock options exercisable within 60 days of March 10, 2026. Helen S. Kim is a senior managing director of the Vida Ventures Funds and may be deemed to share voting and dispositive power over the shares held by the Vida Ventures Funds.

(11) Consists of (i) 4,824,469 shares of common stock held by the EcoR1 Capital Funds, (ii) 1,051,412 shares of Class A common stock held by the EcoR1 Capital Funds and (iii) 4,207 shares of common stock underlying outstanding stock options exercisable within 60 days of March 10, 2026. The EcoR1 Capital Funds are managed by EcoR1 Capital, LLC, which is managed by Oleg Nodelman and as a result he may be deemed to have voting and dispositive power over the securities held by the EcoR1 Capital Funds.

(12) Consists of (i) 19,631 shares of common stock issuable held by Arvala, Inc. and (ii) 68,449 shares of common stock underlying outstanding stock options exercisable within 60 days of March 10, 2026. Lloyd M. Segal is the president of Arvala, Inc. and as a result may be deemed to have voting and dispositive power over the securities held by Arvala, Inc. The business address of Arvala, Inc. is 1681 McGill College, Suite 1200, Montreal Quebec H3A0G6, Canada.

(13) Consists of 23,410 shares of common stock underlying outstanding stock options exercisable within 60 days of March 10, 2026.

(14) Consists of (i) 15,145,281 shares of common stock, (ii) 1,051,412 shares of Class A common stock and (iii) 2,485,054 shares of common stock underlying outstanding stock options exercisable within 60 days of March 10, 2026.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides certain aggregate information with respect to all of our equity compensation plans in effect as of December 31, 2025.

Plan Category	Number of securities to be issued upon exercise of outstanding stock options (a)	Weighted-average exercise price of outstanding stock options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders[1]	5,899,875	$ 5.87	285,723
Equity compensation plans not approved by stockholders	—	—	—
Total	5,899,875	$ 5.87	285,723

(1) Consists of our 2020 Equity Incentive Plan, or the 2020 Plan. The 2026 Equity Incentive Plan, or 2026 Plan, and 2026 Employee Stock Purchase Plan became effective upon the completion of our initial public offering. Following the effectiveness of our 2026 Plan, no further grants will be made under our 2020 Plan. Any outstanding awards granted under our 2020 Plan will remain subject to the terms of our 2020 Plan and applicable award agreements.

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

The following is a description of transactions since January 1, 2024 to which we have been a participant in which the amount involved exceeded or will exceed the lesser of (i) $120,000 or (ii) 1% of the average of our total assets as of each of December 31, 2024 and 2025, and in which any of our directors, executive officers or holders of 5% or more of any class of our capital stock, or any members of their immediately family or affiliated entities, had or will have a direct or indirect material interest, other than compensation arrangements that are described under Part III, Item 11, "Executive Compensation", of this Annual Report.

Initial Public Offering

On January 12, 2026, we closed our IPO pursuant to which we issued and sold an aggregate of 20,297,500 shares of common stock, which included the full exercise by the underwriters of their option to purchase 2,647,500 additional shares at a price to the public of $18.00 per share. The following table sets forth the aggregate cash purchase price of the common stock purchased by our directors, executive officers and 5% stockholders and their affiliates and the number of shares of our common stock issued in consideration of such amounts. Such purchases were made through the underwriters at the initial public offering price of $18.00 per share.

Name	Shares of common stock (#)	Aggregate purchase price ($)
Entities affiliated with MPM BioImpact LLC[(1)]	1,112,777	$ 20,029,986.00
Entities affiliated with VV Manager II, LLC[(2)]	835,000	$ 15,030,000.00
Entities affiliated with EcoR1 Capital, LLC[(3)]	2,222,222	$ 39,999,996.00
Entities affiliated with Blue Owl Capital Holdings LP	277,777	$ 4,999,986.00
Entities affiliated with RA Capital Management, L.P.[(4)]	277,777	$ 4,999,986.00

(1) Consists of (i) 219,897 shares of common stock held by MPM BioVentures 2018, L.P., (ii) 8,689 shares of common stock held by MPM BioVentures 2018 (B), L.P., (iii) 4,284 shares of common stock held by MPM Asset Management Investors BV2018 LLC, (iv) 833,333 shares of common stock held by Oncology Impact Private Investment Fund 2, L.P., and (v) 46,574 shares of common stock held by MPM Oncology Innovations Fund, L.P. Matthew Roden, our President and Chief Executive Officer and a member of our board of directors, is an entrepreneur partner at MPM BioImpact LLC. Todd Foley, a member of our board of directors, is a managing director of MPM BioVentures 2018 LLC, or BV2018 LLC. BV2018 LLC is the Managing Member of MPM BioVentures 2018 GP LLC, which is the General Partner of MPM BioVentures 2018, L.P., and MPM BioVentures 2018(B), L.P. and the Manager of MPM Asset Management Investors BV2018 LLC. Entities affiliated with MPM BioImpact LLC collectively hold more than 5% of our voting securities. MPM BioImpact LLC consists of affiliated entities MPM Asset Management LLC and MPM BioImpact LLC.

(2) Consists of (i) 812,455 shares of common stock held by Vida Ventures II, LLC, or Vida II, and (ii) 22,545 shares of common stock held by Vida Ventures II-A, LLC, or Vida II-A. Vida II and Vida II are collectively referred to as the Vida Ventures Funds. Helen S. Kim, a member of our board of directors, is a senior managing director of the Vida Ventures Funds. Entities affiliated with VV Manager II, LLC collectively hold more than 5% of our voting securities.

(3) Consists of (i) 144,443 shares of common stock held by EcoR1 Capital Fund, L.P., or Capital Fund, and (ii) 2,077,779 shares of common stock held by EcoR1 Capital Fund Qualified, L.P., or Qualified Fund. The Capital Fund and the Qualified Fund are collectively referred to as the EcoR1 Capital Funds. Oleg Nodelman a member of our board of directors, is the founder and portfolio manager of the EcoR1 Capital Funds. Entities affiliated with EcoR1 Capital, LLC collectively hold more than 5% of our voting securities.

(4) Andrew Levin, was a member of our board of directors and is a managing director of funds affiliated with RA Capital Management, L.P.. Andrew Levin resigned from our board of directors immediately prior to the effectiveness of our registration statement on Form S-1.

Series B Redeemable Convertible Preferred Stock Financing

In September 2024, we entered into a preferred stock purchase agreement with certain investors pursuant to which we issued and sold an aggregate of 43,750,000 shares of our Series B redeemable convertible preferred stock at a purchase price of $4.00 per share for aggregate gross proceeds of $175.0 million. Each share of our Series B redeemable convertible preferred stock converted into shares of common stock or Class A common stock immediately prior to the completion of our IPO.

The table below sets forth the aggregate number of shares of Series B redeemable convertible preferred stock purchased by holders of more than 5% of our capital stock as of the date of the closing of the Series B redeemable convertible preferred stock financing and entities affiliated with certain of our executive officers and directors:

Name	Series B redeemable convertible preferred stock (#)	Aggregate purchase price ($)
Entities affiliated with MPM BioImpact LLC[(1)]	6,000,000	$ 24,000,000.00
Entities affiliated with VV Manager II, LLC[(2)]	3,750,000	$ 15,000,000.00
Entities affiliated with EcoR1 Capital, LLC[(3)]	2,500,000	$ 10,000,000.00
Entities affiliated with Blue Owl Capital Holdings LP[(4)]	4,250,000	$ 17,000,000.00
Entities affiliated with RA Capital Management, L.P.[(5)]	5,000,000	$ 20,000,000.00

(1) Consists of (i) 2,541,999 shares of Series B redeemable convertible preferred stock held by MPM BioVentures 2018, L.P., (ii) 135,105 shares of Series B redeemable convertible preferred stock held by MPM BioVentures 2018 (B), L.P., (iii) 50,169 shares of Series B redeemable convertible preferred stock held by MPM Asset Management Investors BV2018 LLC, (iv) 2,727,273 shares of Series B redeemable convertible preferred stock held by Oncology Impact Private Investment Fund 2, L.P., and (v) 545,454 shares of Series B redeemable convertible preferred stock held by MPM Oncology Innovations Fund, L.P. Matthew Roden, our President and Chief Executive Officer and a member of our board of directors, is an entrepreneur partner at MPM BioImpact LLC. Todd Foley, a member of our board of directors, is a managing director of BV2018 LLC. BV2018 LLC is the Managing Member of MPM BioVentures 2018 GP LLC, which is the General Partner of MPM BioVentures 2018, L.P., and MPM BioVentures 2018(B), L.P. and the Manager of MPM Asset Management Investors BV2018 LLC. Entities affiliated with MPM BioImpact LLC collectively hold more than 5% of our voting securities. MPM BioImpact LLC consists of affiliated entities MPM Asset Management LLC and MPM BioImpact LLC.

(2) Consists of (i) 3,648,750 shares of Series B redeemable convertible preferred stock held by Vida II and (ii) 101,250 shares of Series B redeemable convertible preferred stock held by Vida II-A. Helen S. Kim, a member of our board of directors, is a senior managing director of the Vida Ventures Funds. Entities affiliated with VV Manager II, LLC collectively hold more than 5% of our voting securities.

(3) Consists of (i) 102,500 shares of Series B redeemable convertible preferred stock held by the Capital Fund and (ii) 2,397,500 shares of Series B redeemable convertible preferred stock held by the Qualified Fund. Oleg Nodelman a member of our board of directors, is the founder and portfolio manager of the EcoR1 Capital Funds. Entities affiliated with EcoR1 Capital, LLC collectively hold more than 5% of our voting securities.

(4) Consists of (i) 4,101,478 shares of Series B redeemable convertible preferred stock held by Blue Owl Healthcare Opportunities IV LP and (ii) 148,522 shares of Series B redeemable convertible preferred stock held by Blue Owl Healthcare Opportunities EF IV LP. Blue Owl Healthcare Opportunities Advisors LLC, an indirect subsidiary of Blue Owl Capital Holdings LP, is the investment manager of the Blue Owl Healthcare Holders. Blue Owl Healthcare Opportunities GP IV LLC is the general partner of the Blue Owl Healthcare Holders.

(5) Consists of (i) 4,000,000 shares of Series B redeemable convertible preferred stock held by RA Capital Healthcare Fund, L.P., and (ii) 1,000,000 shares of Series B redeemable convertible preferred stock held by RA Capital Nexus Fund III, L.P., or collectively, the RA Capital Funds. Andrew Levin, was a member of our board of directors and is a managing director of the RA Capital Funds. Andrew Levin resigned from our board of directors immediately prior to the effectiveness of our registration statement on Form S-1.

Eli Lilly and Company Research and Collaboration Agreement

In May 2024, we entered into the Collaboration Agreement with Eli Lilly, a holder of more than 5% of our capital stock, to generate anticancer radiopharmaceuticals using our novel miniprotein technology platform. Pursuant to the Collaboration Agreement, we granted Eli Lilly an exclusive (even as to us and our affiliates), royalty-bearing, worldwide license, with the right to sublicense, to certain of our patents and other intellectual property rights to exploit certain compounds and therapeutic or diagnostic products that contain such compounds solely as products that contain a radioactive isotope. We also granted Eli Lilly a non-exclusive, royalty-bearing, worldwide license, with the right to sublicense, to the intellectual property necessary or useful to exploit the licensed compounds and licensed products solely as products that contain a radioactive isotope and a non-exclusive, fully paid-up license, with the right to sublicense, to exploit certain other intellectual property developed under the Collaboration Agreement for any and all purposes (subject to certain limitations). In addition, we and Eli Lilly agreed to negotiate in good faith to enter into a separate agreement in the event the parties agree that the clinical development of a licensed compound requires, or would be benefited by, a license to one of our other compounds. Eli Lilly may, at any time in its sole discretion and without cause, terminate the Collaboration Agreement on a collaboration target-by-collaboration target or region-by- region basis (or any combination thereof) upon 60 days' prior written notice to us.

Under the Collaboration Agreement, Eli Lilly may designate a specified number of initial collaboration targets, with the right to substitute other targets. We will be responsible for research activities through initial human imaging studies for a lead candidate for each selected target, and Eli Lilly will thereafter be responsible for regulatory filings, clinical development and commercialization activities worldwide. There is a separate research plan for each collaboration target, and our development costs are capped, on a research plan-by-research plan basis. Eli Lilly will reimburse our reasonable out-of-pocket costs and full-time equivalent costs incurred in excess of the cap.

Eli Lilly paid us an upfront license fee of $60.0 million as a nonrefundable cash payment upon execution of the Collaboration Agreement. The Collaboration Agreement requires Eli Lilly to pay up to an aggregate of $525.0 million upon achievement of certain research development, regulatory and commercial launch milestones and up to an aggregate of $630.0 million upon achievement of certain sales milestones. As of December 31, 2025, one development milestone under the Collaboration Agreement totaling $1.0 million was achieved. In addition, if Eli Lilly successfully commercializes a therapeutic or diagnostic product under the Collaboration Agreement, Eli Lilly is required, unless earlier terminated, to pay us tiered royalties of up to 10% based on annual net sales, on a product-by-product and country-by-country basis, subject to specified reductions, until the later of the expiration of licensed patent rights in a country, expiration of regulatory exclusivity, or ten years after the first product sale in such country. The Collaboration Agreement requires Eli Lilly to use commercially reasonable efforts to develop and commercialize a licensed product from a research program in certain markets and through satisfaction of certain criteria. For further details see the section titled "*Business—License and collaboration agreements*" included elsewhere in this Annual Report.

Royalty Transfer Agreement with MPM Oncology Charitable Foundation and UBS Optimus Foundation

In August 2020, we entered into the Royalty Transfer Agreement, with MPM Charitable Foundation, an affiliate of a stockholder holding more than 5% of our total outstanding stock, and UBS (together with MPM Charitable Foundation, the "Charitable Foundations"). Pursuant to the Royalty Transfer Agreement, we will pay 0.5% of annual global net sales to each of the Charitable Foundations, for a total of 1.0% of net sales, subject to customary reductions, for products that incorporate or utilize intellectual property that was discovered or developed by us prior to our IPO. Our payment obligations for each product will continue on a country-by-country basis upon the later of the twelfth anniversary of the first commercial sale of such product in such country or the expiration of the last to expire of certain patents owned or controlled by us covering such products in such country.

Our payment obligations to MPM Charitable Foundation will terminate immediately upon authorization of the MPM Charitable Foundation's board of directors (or similar body) or upon the winding up or dissolution of MPM Charitable Foundation. Our payment obligations to UBS will terminate immediately upon the winding up of Oncology Impact Fund 2, L.P., a Cayman Islands exempt limited partnership which is associated with MPM Charitable Foundation.

Consulting and Management Services with MPM BioImpact LLC

We have received consulting and management services from entities affiliated with MPM BioImpact LLC, a holder of more than 5% of our capital stock. In connection with the services, the costs incurred for the year ended December 31, 2025 were de minimis and $0.1 million for the year ended December 31, 2024.

Investors' Rights, Voting and Right of First Refusal Agreements

In connection with our Series B preferred stock financing, we entered into an amended and restated investors' rights agreement, the Voting Agreement and an amended and restated right of first refusal and co-sale agreement, containing registration rights, information rights, rights of first offer, voting rights and rights of first refusal, among other things, with certain holders of our capital stock, including the MPM BioImpact Funds, the Vida Ventures Funds, the EcoR1 Capital Funds, the RA Capital Funds, entities affiliated with Blue Owl Capital Holdings LP and Eli Lilly & Company.

The foregoing stockholder agreements terminated upon the closing of our IPO, except for the registration rights granted under our amended and restated investors' rights agreement.

Employment arrangements

We have entered into employment agreements with our executive officers. For more information regarding such employment agreements, see Part III, Item 11, "Executive Compensation—Narrative Disclosure to Summary Compensation Table—Arrangements with Executive Officers", of this Annual Report.

Equity Grants

We have granted options to purchase shares of our common stock to certain of our executive officers and directors. For more information regarding the options granted to our executive officers and directors, see Part III, Item 11, "Executive Compensation—Non-Employee Director Compensation", of this Annual Report.

Indemnification agreements

We have entered into indemnification agreements with our current directors and executive officers. The indemnification agreements and our amended and restated certificate of incorporation and amended and restated bylaws require us to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. For more information regarding these agreements, see Part III, Item 11, "Executive Compensation—Limitations on Liability and Indemnification", of this Annual Report.

Related person transaction policy

Our board of directors has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds in any fiscal year the lesser of (i) $120,000 or (ii) 1% of the average of our total assets at year end for the last two completed fiscal years and a related person had, has or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked with considering all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

Director Independence

Under the Nasdaq Listing Rules, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of its initial public offering. In addition, the Nasdaq Listing Rules require that, subject to specified exceptions, each member of a listed company's audit and compensation committees be independent and that director nominees be selected or recommended for the board's selection by independent directors constituting a majority of the independent directors or by a nominating and corporate governance committee comprised solely of independent directors. Under the Nasdaq Listing Rules, a director will only qualify as "independent" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that such person is "independent" as defined under the Nasdaq Listing Rules and the rules under the Exchange Act.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Matthew Roden and Todd Foley, is an "independent director" as defined under the Nasdaq Listing Rules, including, in the case of all the members of our audit committee, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act and are "non-employee directors" as defined in Section 16b-3 of the Exchange Act. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in Part III, Item 13, "Certain Relationships and Related Transactions, and Director Independence" of this Annual Report.

Item 14. Principal Accounting Fees and Services.

Audit and All Other Fees

The following table presents fees for professional audit services and other services rendered to us by Deloitte & Touche LLP, (PCAOB Auditor ID No. 34), our independent registered public accounting firm, for the years ended December 31, 2025 and 2024.

	Year Ended December 31,	
Description of Services Provided by Deloitte	**2025**	**2024**
Audit fees	$ 864,940	$ 917,328
Audit related fees	—	—
Tax fees	—	—
All other fees	—	—
Total fees	$ 864,940	$ 917,328

Audit Committee Pre-Approval of Audit and Non-Audit Services

Our audit committee has established a policy governing our use of the services of our independent registered public accounting firm. Under the policy, our audit committee is required to pre-approve all audit and permissible non-audit services performed by our independent registered public accounting firm in order to ensure that the provision of such services does not impair such accounting firm's independence. The pre-approval of services may be delegated to the chairperson of the audit committee, but the decision must be reported to the full audit committee at its next scheduled meeting.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Financial Statements.

For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(2) Financial Statement Schedules.

All financial schedules have been omitted because the required information is either presented in the consolidated financial statements or the notes thereto or is not applicable or required.

(3) Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed on January 12, 2026).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K, filed on January 12, 2026).
4.1+	Third Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated September 20, 2024 (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on December 19, 2025).
4.2	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.2 of Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on January 5, 2026).
4.3*	Description of Registrant's Securities.
10.1#	2020 Equity Incentive Plan, and forms of award agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on December 19, 2025).
10.2#	2026 Equity Incentive Plan, and forms of awards thereunder (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-8 (File No. 333-292679), filed on January 12, 2026).
10.3#	2026 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-8 (File No. 333-292679), filed on January 12, 2026).
10.4#	Senior Executive Cash Incentive Plan (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on December 19, 2025).
10.5#	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.5 of Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on January 5, 2026).
10.6#	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on December 19, 2025).
10.7#	Employment Agreement, dated December 18, 2025, between the Registrant and Matthew Roden (incorporated by reference to Exhibit 10.7 of Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on January 5, 2026).
10.8#	Employment Agreement, dated December 18, 2025, between the Registrant and Kyle D. Kuvalanka (incorporated by reference to Exhibit 10.8 of Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on January 5, 2026).
10.9#	Employment Agreement, dated December 18, 2025, between the Registrant and Shulamit Ron-Bigger (incorporated by reference to Exhibit 10.9 of Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on January 5, 2026).
10.10#	Employment Agreement, dated December 18, 2025, between the Registrant and Paul L. Feldman (incorporated by reference to Exhibit 10.10 of Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on January 5, 2026).
10.11#	Employment Agreement, dated December 18, 2025, between the Registrant and Akos Czibere (incorporated by reference to Exhibit 10.11 of Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on January 5, 2026).
10.12#	Employment Agreement, dated December 18, 2025, between the Registrant and Tyler Benedum (incorporated by reference to Exhibit 10.12 of Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on January 5, 2026).

10.13+	License, Research and Collaboration Agreement, dated May 16, 2024, between the Registrant and Eli Lilly and Company (incorporated by reference to Exhibit 10.11 of the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on December 19, 2025).
10.14+	License Agreement, dated November 1, 2021, between the Registrant and Institute for Protein Innovation, Inc (incorporated by reference to Exhibit 10.12 of the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on December 19, 2025).
10.15	Royalty Transfer Agreement, dated August 27, 2020, among the Registrant (formerly known as HotKnot Therapeutics, Inc.), MPM Oncology Charitable Foundation, Inc. and the UBS Optimus Foundation (incorporated by reference to Exhibit 10.13 of the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on December 19, 2025).
10.16+	Lease Agreement, dated January 13, 2022, between the Registrant and IDB 17-19 Drydock Limited Partnership (incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on December 19, 2025).
10.17+	First Amendment to Lease Agreement, dated February 1, 2023, between the Registrant and IDB 17-19 Drydock Limited Partnership (incorporated by reference to Exhibit 10.15 of the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on December 19, 2025).
10.18*+	Second Amendment to Lease Agreement, dated April 14, 2025, between the Registrant and IDB 17-19 Drydock Limited Partnership.
19.1*	Insider Trading Policy.
21.1	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-292283), filed on December 19, 2025).
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting form.
24.1*	Power of Attorney (included on the signature page to this Report).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
32.1†	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1*	Compensation Clawback Policy.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
# Indicates management contract or compensatory plan.
+ Portions of this exhibit (indicated by asterisks) have been redacted pursuant to Item 601 of Regulation S-K because they are both not material and the registrant customarily and actually treats such information as private or confidential.
† Furnished herewith.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Aktis Oncology, Inc.

Date: March 30, 2026

By: /s/ Matthew Roden
Matthew Roden, PhD
President, Chief Executive Officer

POWER OF ATTORNEY

Know All Persons By These Presents, that each person whose signature appears below constitutes and appoints Matthew Roden, PhD and Kyle D. Kuvalanka, and each or any one of them, as his or her true and lawful attorneys-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign 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 requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

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

NAME	TITLE	DATE
/s/ Matthew Roden Matthew Roden, PhD	Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2026
/s/ Kyle D. Kuvalanka Kyle D. Kuvalanka	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2026
/s/ Todd Foley Todd Foley, MBA	Director and Chair	March 30, 2026
/s/ Ken Herrmann Ken Herrmann, MD	Director	March 30, 2026
/s/ Helen S. Kim Helen S. Kim, MBA	Director	March 30, 2026
/s/ Oleg Nodelman Oleg Nodelman	Director	March 30, 2026
/s/ Lloyd M. Segal Lloyd M. Segal, MBA	Director	March 30, 2026
/s/ Michael A. Sherman Michael A. Sherman	Director	March 30, 2026
/s/ Mary Thistle Mary Thistle	Director	March 30, 2026

Exhibit 4.3

Description of Securities of Aktis Oncology, Inc.

The following is a summary of the capital stock of Aktis Oncology, Inc. ("Aktis," the "Company," "our," "we" or "us") and certain provisions of our amended and restated certificate of incorporation (the "Restated Charter"), and our amended and restated bylaws (the "Restated Bylaws"), and certain provisions of Delaware law. This summary does not purport to be complete and is qualified by reference to our Restated Charter and Restated Bylaws, current copies of which are filed as exhibits to our most recent Annual Report on Form 10-K.

General

Our Restated Charter authorizes us to issue up to 480,000,000 shares of common stock, $0.0001 par value per share, 10,000,000 shares of Class A common stock, $0.0001 par value per share and 10,000,000 shares of preferred stock, $0.0001 par value per share, all of which shares of preferred stock will be undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

Common Stock and Class A Common Stock

Our Restated Charter authorizes the issuance of up to 480,000,000 shares of our common stock and 10,000,000 shares of our Class A common stock.

The holders of our common stock and our Class A common stock have identical rights, provided that, (i) except as otherwise expressly provided in our Restated Charter or as required by applicable law, on any matter that is submitted to a vote by our stockholders, holders of our common stock are entitled to one vote per share of common stock, and holders of our Class A common stock are not entitled to any votes per share of Class A common stock, including for the election of directors, and (ii) holders of our common stock have no conversion rights, while holders of our Class A common stock shall have the right to convert each share of our Class A common stock into one share of common stock at such holder's election, provided that as a result of such conversion, such holder, together with its affiliates and any members of a Schedule 13(d) group with such holder, would not beneficially own in excess of 4.99% of our common stock immediately prior to and following such conversion, unless otherwise as expressly provided for in our Restated Charter. However, the beneficial ownership limitation may be increased or decreased to any other percentage (not to exceed 19.99%) designated by such holder of Class A common stock upon 61 days' notice to us.

Voting Rights

Our common stock is entitled to one vote per share on any matter that is submitted to a vote of our stockholders, except on matters relating solely to terms of preferred stock, and our Class A common stock is not entitled to any votes per share. However, as long as any shares of Class A common stock are outstanding, we will not, without the affirmative vote of the holders of a majority of the then outstanding shares of Class A common stock, alter or change adversely the powers, preferences or rights given to the Class A common stock.

Except as otherwise expressly provided in our Restated Charter or required by applicable law, all shares of common stock and Class A common stock have the same rights and privileges and rank

equally, share ratably, and be identical in all respects for all matters, including those described below. Our Restated Charter does not provide for cumulative voting in the election of directors.

Dividends

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock and Class A common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available therefor if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine.

Liquidation rights

In the event of our liquidation, dissolution or winding-up, the holders of our common stock and Class A common stock will be entitled to share equally, identically, and ratably in all assets remaining after payment of or provision for any liabilities, liquidation preferences and accrued or declared but unpaid dividends, if any, with respect to any outstanding preferred stock, unless a different treatment is approved by the affirmative vote of the holders of a majority of the outstanding shares of such affected class, voting separately as a class.

Other Rights

The holders of our common stock and Class A common stock have no preemptive rights. There are no redemption or sinking fund provisions applicable to our common stock and Class A common stock.

Preferred Stock

Under the terms of our Restated Charter, our board of directors is authorized to direct us to issue up to 10,000,000 shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from seeking to acquire, a majority of our outstanding voting stock.

We have no present plans to issue any shares of preferred stock.

Registration Rights

The holders of the shares of 34,027,218 shares of common stock which includes all common stock issued upon the automatic conversion of our redeemable convertible preferred stock outstanding immediately prior to the closing of our initial public offering in January 2026 (the "IPO") and the shares of common stock issuable upon the conversion of Class A common stock issued upon conversion of our redeemable convertible preferred stock upon closing of the IPO, are

entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to an amended and restated investors' rights agreement by and among us and certain investors (the "Investors' Rights Agreement" and such securities, the "Registrable Securities"). The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

Demand Registration Rights

At any time beginning 180 days following the completion of the IPO, the holders of a majority of Registrable Securities then outstanding have the right to demand that we file a registration statement covering at least 40% of the Registrable Securities then outstanding. These registration rights are subject to specified conditions and limitations, including the right of the underwriters, if any, to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we are required to effect the registration as soon as practicable, but in any event no later than 60 days after the receipt of such request; provided, however, that we will not be required to effect such a registration if, among other things, we have already effected two registrations for the holders of registrable securities in response to these demand registration rights.

Piggyback Registration Rights

If we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders, the holders of Registrable Securities will each be entitled to notice of the registration and will be entitled to include their shares of common stock in the registration statement. These piggyback registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under specified circumstances.

Registration on Form S-3

At any time after we become eligible to file a registration statement on Form S-3, the holders of Registrable Securities then outstanding will be entitled to request to have such shares registered by us on a Form S-3 registration statement. These Form S-3 registration rights are subject to other specified conditions and limitations, including the condition that the anticipated aggregate offering price, net of certain selling expenses, is at least $5.0 million. Upon receipt of this request, the holders of registrable securities will each be entitled to participate in this registration. Upon such a request, we are required to effect the registration as soon as practicable, but in any event no later than 45 days after the receipt of such request; provided, however, that we will not be required to effect such a registration if, among other things, we have already effected two registrations on Form S-3 for the holders of Registrable Securities in response to these demand registration rights within the preceding 12 months.

Expenses of Registration

We are required to pay all expenses, including fees and expenses of one counsel to represent the selling stockholders (up to $75,000 total), relating to any demand, piggyback or Form S-3 registration, other than underwriting discounts and commissions, stock transfer taxes and any additional fees of counsel for the selling stockholders, subject to specified conditions and

limitations. We are not required to pay registration expenses if a demand registration request is withdrawn at the request of a majority of holders of registrable securities to be registered, unless holders of a majority of the registrable securities agree to forfeit their right to one demand registration.

The Investors' Rights Agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions in the applicable registration statement attributable to us, and the selling stockholders are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them, subject to certain limitations.

Termination of Registration Rights

The registration rights granted under the Investors' Rights Agreement will terminate with respect to any particular stockholder upon the earlier of (a) the closing of a liquidation event, in which the consideration received by the stockholders is in the form of cash and/or publicly traded securities, or if the stockholders receive registration rights from the acquiring company or other successor to us that are reasonably comparable to those granted under the Investors' Rights Agreement, (b) with respect to each stockholder, at such time such stockholder, together with its "affiliates" (as that term is defined in Rule 144 under the Securities Act) holds less than 1% of our outstanding capital stock and is able to sell all of its shares pursuant to Rule 144 or another similar exemption under the Securities Act during a three-month period without registration and (c) the third anniversary of the closing of the IPO.

Anti-Takeover Effects of our Restated Charter and our Restated Bylaws

Section 203 of the Delaware General Corporation Law

Our Restated Charter and Restated Bylaws contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of our board of directors but which may have the effect of delaying, deferring or preventing a future takeover or change in control of us unless such takeover or change in control is approved by our board of directors.

These provisions include:

Classified Board

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

Action by Written Consent; Special Meetings of Stockholders

Our Restated Charter provides that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our Restated Charter and the Restated Bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can only be called pursuant to a resolution adopted by a

majority of our board of directors. Except as described above, stockholders will not be permitted to call a special meeting or to require our board of directors to call a special meeting.

Removal of Directors

Our Restated Charter provides that our directors may be removed only for cause by the affirmative vote of at least two-thirds of the voting power of our outstanding shares of capital stock, then entitled to vote thereon voting together as a single class. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board of directors.

Advance Notice Procedures

Our Restated Bylaws establishes an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors. Stockholders at an annual meeting are only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the Restated Bylaws do not give our board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the Restated Bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Supermajority Approval Requirements

Delaware General Corporation Law (the "DGCL") generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires a greater percentage. Our Restated Charter and Restated Bylaws provide that the affirmative vote of holders of at least 75% of the total votes eligible to be cast in the election of directors are required to amend, alter, change or repeal specified provisions. This requirement of a supermajority vote to approve amendments to our Restated Charter and Restated Bylaws could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but Unissued Shares

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

Choice of Forum

Our Restated Bylaws provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of, or a claim based on, a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees or stockholders to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the the DGCL, or our Restated Charter or Restated Bylaws (including the interpretation, validity or enforceability thereof) or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim governed by the internal affairs doctrine.

However, Section 27 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Consequently, this choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction or the Securities Act. Moreover, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

In addition, our Restated Bylaws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying a particular offering.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, our Restated Bylaws provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

Section 203 of the DGCL

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

years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

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

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

Limitations of Liability and Indemnification Matters

Our Restated Charter contains provisions that limit the liability of our current and former directors and officers for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors and officers of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors or officers, except liability for:

- any breach of the director's or officer's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- as a director, unlawful payments of dividends or unlawful stock repurchases or redemptions;
- as an officer, derivative claims brought on behalf of the corporation by a stockholder; or
- any transaction from which the director or officer derived an improper personal benefit.

Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our Restated Charter authorizes us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our Restated Bylaws provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our Restated Bylaws also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into

agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding.

We believe that these Restated Charter and Restated Bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our Restated Charter and Restated Bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent's address is 150 Royall Street, Canton, Massachusetts 02021.

Listing

Our common stock is listed on the Nasdaq Global Select Market under the trading symbol "AKTS."

Exhibit 10.18

CERTAIN INFORMATION CONTAINED IN THIS EXHIBIT, MARKED BY [***], HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE REGISTRANT HAS DETERMINED THAT IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

SECOND AMENDMENT TO LEASE

THIS SECOND AMENDMENT TO LEASE (this "**Second Amendment**") is made and entered into as of April 14, 2025 (the "**Execution Date**"), by and between **IDB 17-19 DRYDOCK LIMITED PARTNERSHIP**, a Delaware limited partnership ("**Landlord**") and **AKTIS ONCOLOGY, INC.**, a Delaware corporation ("**Tenant**").

WHEREAS, Landlord and Tenant are parties to that certain Lease dated January 13, 2022, as amended by a First Amendment to Lease dated as of February 1, 2023 (the "**First Amendment**") (collectively, the "**Existing Lease**") with respect to premises containing, in the aggregate, approximately 17,944 rentable square feet comprised of: (i) approximately 17,767 rentable square feet located on the fourth (4th) floor (the "**Existing Fourth Floor Premises**"); and (ii) approximately 177 rentable square feet located on the first (1st) floor comprised of chemical storage space (collectively, the "**Existing Premises**", each within the Building located at One Design Place, Boston, Massachusetts (the "**Building**"), as more particularly described therein. In addition, Tenant has the use of the Rooftop Area (as defined in the First Amendment). All capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Existing Lease. The Existing Lease, as modified and amended by this Second Amendment, is referred to herein as the "**Lease**."

WHEREAS, Tenant desires to lease additional premises immediately adjacent to the Existing Fourth Floor Premises containing 625 rentable square feet on the fourth (4th) floor of the Building (the "**Expansion Premises**") for the use by Tenant of an H Room, a gas storage room, and for one-half of Tenant's quality control room. The Existing Fourth Floor Premises and the Expansion Premises shall equal a total of 18,392 rentable square feet, as shown on Exhibit A, Second Amendment, a copy of which is attached hereto and incorporated by reference herein.

WHEREAS, Landlord agrees to lease the Expansion Premises to Tenant on the terms and conditions hereinafter set forth.

WHEREAS, all capitalized terms used but not otherwise defined herein shall have the meanings ascribed to them in the Existing Lease.

NOW THEREFORE, in consideration of Ten Dollars ($10.00) and other good and valuable consideration, the receipt, sufficiency and delivery of which are hereby acknowledged, the parties hereby agree that the Lease is hereby amended as follows:

1. **Demise of the Expansion Premises**. Landlord hereby demises and leases to Tenant, and Tenant hereby leases from Landlord, the Expansion Premises, for the period of time commencing as of the date that the issuance of a building permit for Tenant's intended alterations to the Existing Fourth Floor Premises and Expansion Premises is delivered (the "**Expansion Premises Commencement Date**") and expiring the Expiration Date (as defined in the Existing Lease), unless sooner terminated in accordance with the terms of the Lease. Commencing as of

the Expansion Premises Commencement Date, any reference to the term "Premises" in the Lease shall be deemed to mean both the Existing Premises and the Expansion Premises. The demise of the Expansion Premises shall be upon all of the same terms and conditions of the Existing Lease, except as set forth herein. Effective as of the Expansion Premises Commencement Date, the Expansion Premises shall be deemed to be part of the Premises and all references in the Lease to the "Leased Premises" shall include both the Existing Premises and the Expansion Premises.

2. **Base Rent**. Commencing as of the Expansion Premises Commencement Date, Base Rent with respect to the Expansion Premises shall be payable monthly, as provided in Section 2.4 of the Lease, as follows:

[***]

3. **Operating Costs**. Tenant shall pay, as Additional Rent with respect to the Expansion Premises, Tenant's Proportionate Share of Operating Costs (which include Taxes) in accordance with Section 2.4 of the Lease. Tenant's Proportionate Share with respect to the Expansion Premises shall mean 0.11% (625 SF / 553,245 SF).

4. **Condition of Expansion Premises**. Tenant shall lease the Expansion Premises "as-is", in the condition in which the Expansion Premises are in as of the Expansion Premises Commencement Date, without any obligation on the part of Landlord with respect thereto and without any representation or warranty to Tenant as to the condition of the Expansion Premises. Any work to be performed by Tenant in connection with Tenant's occupancy of the Expansion Premises shall be considered "alterations" and shall be performed in accordance with the Existing Lease, including, without limitation, Section 4.2 thereof.

5. **Electricity**. In connection with Tenant's lease of the Expansion Premises, commencing as of the Expansion Premises Commencement Date, Landlord shall grant to Tenant an additional wattage of normal power, in addition to Tenant's allotment granted to Tenant in accordance with Section 2.8 of the Existing Lease, and is as described on Exhibit B, Second Amendment, attached hereto.

6. **Security Deposit**. The parties hereby acknowledge that Landlord is currently holding a security deposit in the form of a Letter of Credit in the amount of $897,120.00, pursuant to Article I, Basic Lease Information and Section 6.5 of the Lease. The parties hereby further acknowledge that Landlord shall continue to hold the Letter of Credit in accordance with Section 6.5 of the Lease.

7. **Landlord's Notice Address**. For all purposes of the Lease, the fourth notice address for Landlord as set forth in Section 7.4 of the Lease is deleted and the following is substituted in its place:

Goulston & Storrs PC
One Post Office Square, Floor 25
Boston, Massachusetts 02109
Attn: [***]
Email: [***]

8. **Inapplicable Lease Provisions**. Section 2 of the Lease (Landlord's Work) and Exhibit F-2 to the Lease (Landlord/Tenant Matrix) shall have no applicability with respect to this Second Amendment.

9. **Representations and Warranties**. Each of Landlord and Tenant hereby represents and warrants to the other that it has the full right, power and authority to enter into this Second Amendment and to perform its obligations hereunder, and that upon execution of this Second Amendment by such party, this Second Amendment shall constitute a valid and legally binding obligation of such party. Landlord represents and warrants that this Amendment is not subject to any review or consent by any third parties, including, without limitation, any lender of Landlord or that if such lender or third party consent is required that Landlord has obtained such consent.

10. **Ratification, Approval and Confirmation of Terms**. In all respects, the Existing Lease, as hereby amended and modified, is hereby ratified, approved and confirmed.

11. **Broker**. Each of Landlord and Tenant hereby warrant and represent to the other that it has dealt with no broker in connection with this Second Amendment. Each of Landlord and Tenant hereby agree to defend, indemnify, and hold harmless the other, from and against any claim by third parties for brokerage, commissions, finders or other fees relative to this Second Amendment or the leasing of space in the Building (except as otherwise provided in the Existing Lease), and any court costs, attorneys' fees or other costs or expenses arising therefrom, alleged to be due from such indemnifying party by any broker.

12. **Counterparts**. This Second Amendment is executed in any number of counterparts, each copy of which is identical, and any one of which shall be deemed to be complete in itself and may be introduced in evidence or used for any purpose without the production of the other copies. This Second Amendment may be executed by electronic signature, which shall be considered as an original signature for all purposes and shall have the same force and effect as an original signature. Without limitation, in addition to electronically produced signatures, "electronic signature" shall include faxed versions of an original signature or electronically scanned and transmitted versions (e.g., via pdf) of an original signature or signatures via electronic signature program (e.g., DocuSign or AdobeSign). This Second Amendment may be executed in several counterparts, each of which shall be an original, but all of which shall constitute but one and the same instrument.

13. **Miscellaneous.** This Second Amendment shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts without regard to its conflict of law provisions and shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. In the event of any inconsistency or conflict between the terms of this Second Amendment and of the Existing Lease, the terms of this Second Amendment shall control. Time is of the essence of all of the terms of this Second Amendment. This Second Amendment constitutes and contains the sole and entire agreement of the parties hereto with respect to the subject matter hereof. This Second Amendment may not be changed, modified, discharged or terminated orally in any manner other than by an agreement in writing signed by Tenant and Landlord or their respective representatives, successors and permitted assigns. Submission of this Second Amendment by Landlord is not an officer to enter in this

Second Amendment but rather is a solicitation for such an offer by Tenant. Landlord shall not be bound by this Second Amendment until Landlord has executed and delivered the same to Tenant.

[signatures on following page]

IN WITNESS WHEREOF, the parties have caused this Second Amendment to be duly authorized, executed and delivered as of the First Amendment Effective Date.

LANDLORD:

IDB 17-19 DRYDOCK LIMITED PARTNERSHIP,
a Delaware limited partnership

By: /s/ Dana Griffin
Name: Dana Griffin
Title: Authorized Signatory

TENANT:

AKTIS ONCOLOGY, INC.,
a Delaware corporation

By: /s/ Matthew Roden
Name: Matthew Roden
Title: CEO

REVISED EXHIBIT A, SECOND AMENDMENT
PLAN OF EXISTING FOURTH FLOOR PREMISES AND EXPANSION PREMISES

[***]

EXHIBIT B, SECOND AMENDMENT
ALLOTMENT OF ELECTRICITY

[***]

Exhibit 19.1

AKTIS ONCOLOGY, INC.

INSIDER TRADING POLICY

Aktis Oncology, Inc. (the "Company") has adopted the following policy and procedures for securities trading by Company directors and employees (our "Insider Trading Policy"). Our Insider Trading Policy is intended to prevent the misuse of material nonpublic information, insider trading in securities, and the severe consequences associated with violations of insider trading laws. It is your obligation to review, understand and comply with this Insider Trading Policy and applicable laws. Our Board of Directors has approved this Insider Trading Policy, and we have appointed Kyle Kuvalanka as the Compliance Officer (with their designees, the "Compliance Officer") to administer the policy and to be available to answer your questions.

PART I. OVERVIEW

A. Who Must Comply?

This Insider Trading Policy applies to all of our employees and members of our Board of Directors, including anyone employed by or acting as a director of any of the Company's subsidiaries, as well as any other individuals whom the Compliance Officer may designate as Insiders (defined below) because they have access to material nonpublic information about the Company.

In addition, all of our directors, executive officers (as defined by Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) and other designated employees must comply with the Trading Procedures included in Part II of this Insider Trading Policy (the "Trading Procedures"); we will refer to these individuals in this policy as "Insiders." The Trading Procedures provide rules for when Insiders can trade in our securities and explain the process for mandatory pre-clearance of proposed trades. You will be notified if you are considered to be an Insider who is required to comply with the Trading Procedures.

This Insider Trading Policy and, for Insiders, the Trading Procedures also apply to the following persons ("Affiliated Persons"):

- your "Family Members" ("Family Members" are (a) your spouse or domestic partner, children, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws who reside in the same household as you, (b) your children or your spouse's children who do not reside in the same household as you but are financially dependent on you, (c) any of your other family members who do not reside in your household but whose transactions are directed by you, and (d) any other individual over whose account you have control and to whose financial support you materially

contribute. (Materially contributing to financial support would include, for example, paying an individual's rent but not just a phone bill.));

- all trusts, family partnerships and other types of entities formed for your benefit or for the benefit of a member of your family and over which you have the ability to influence or direct investment decisions concerning securities;

- all persons who execute trades on your behalf; and

- all investment funds, trusts, retirement plans, partnerships, corporations and other types of entities over which you have the ability to influence or direct investment decisions concerning securities; provided, however, that the Trading Procedures do not apply to any such entity that engages in the investment of securities in the ordinary course of its business (e.g., an investment fund or partnership) if the entity has established its own insider trading controls and procedures in compliance with applicable securities laws and it (or an affiliated entity) has represented to the Company that its affiliated entities: (a) engage in the investment of securities in the ordinary course of their respective businesses; (b) have established insider trading controls and procedures in compliance with securities laws; and (c) are aware the securities laws prohibit any person or entity who has material nonpublic information concerning the Company from purchasing or selling securities of the Company or from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell securities.

You are responsible for ensuring compliance with this Insider Trading Policy, including the Trading Procedures contained herein, by all of your Affiliated Persons.

B. What is Prohibited by this Insider Trading Policy?

You and your Affiliated Persons are prohibited from engaging in insider trading and from trading in securities in violation of this Insider Trading Policy. "Insider trading" is (1) trading (buying or selling) the securities of a company whether for your account or for the account of another, while in the possession of material nonpublic information (see definition below) about that company or (2) disclosing material nonpublic information about a company to others who may trade on the basis of that information. Insider trading can result in criminal prosecution, jail time, significant fines and public embarrassment for you and the Company.

Prohibition on Trading in Company Securities

When you are in possession of material nonpublic information about the Company, whether positive or negative, you are prohibited from trading (whether for your account of for the account of another) in the Company's securities, which includes common stock, options to purchase common stock, any other type of securities that the Company may issue (such as preferred stock, convertible debentures, warrants and exchange-traded options), and any derivative securities that provide the economic equivalent of ownership of any the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of the Company's securities, except for trades made

pursuant to plans approved by the Compliance Officer in accordance with this policy that are intended to comply with Rule 10b5-1 under the Exchange Act.

The trading prohibitions in this Insider Trading Policy do not apply to: (1) an exercise of an employee stock option when payment of the exercise price is made in cash or (2) the withholding by the Company of shares of stock upon vesting of restricted stock or upon settlement of restricted stock units to satisfy applicable tax withholding requirements if (a) such withholding is required by the applicable plan or award agreement or (b) the election to exercise such tax withholding right was made by the Insider in compliance with the Trading Procedures.

The trading prohibitions in this Insider Trading Policy do apply, however, to the use of outstanding Company securities to pay part or all of the exercise price of a stock option, any sale of stock as part of a broker-assisted cashless exercise of an option and any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

Prohibition on Tipping

Providing material nonpublic information about the Company to another person who may trade or advise others to trade on the basis of that information is known as "tipping" and is illegal. You are prohibited from providing material nonpublic information about the Company to a friend, relative or anyone else who might buy or sell a security or other financial instrument on the basis of that information, whether or not you intend to or actually do realize a profit (or any other benefit) from such tipping. Additionally, you are prohibited from recommending to any person that such person engage in or refrain from engaging in any transaction involving the Company's securities, or otherwise give trading advice concerning the Company's securities, if you are in possession of material nonpublic information about the Company.

Prohibition on Trading in Securities of Other Companies

This policy's prohibitions against insider trading and tipping also apply to trading in securities of other companies, including the Company's customers, suppliers, partners and other enterprises with which we are working (such as when negotiating an acquisition, investment or other transaction that could be material to the other company). Whenever, during the course of your service to or employment by the Company, you become aware of material nonpublic information about another company, including any confidential information that is reasonably likely to affect the market price of that company's securities (for example, discussions of licensing a product or acquiring that other company), neither you nor your Affiliated Persons may trade in any securities of that company, give trading advice about that company, tip or disclose that information, pass it on to others or engage in any other action to take advantage of that information.

If your work regularly involves handling or discussing confidential information of one of our partners, suppliers or customers, you should consult with the Compliance Officer before trading in any of that company's securities.

Other Prohibited Transactions

- ***No Short Sales***. You may not at any time sell any securities of the Company that are not owned by you at the time of the sale (a "short sale").

- ***No Purchases or Sales of Derivative Securities or Hedging Transactions***. You may not buy or sell puts, calls, other derivative securities of the Company or any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of our securities or engage in any other hedging transaction with respect to our securities.

- ***No Company Securities Subject to Margin Calls***. You may not use the Company's securities as collateral in a margin account.

- ***No Pledges***. You may not pledge Company securities as collateral for a loan (or modify an existing pledge).

Duration of Trading Prohibitions

These trading prohibitions continue whenever and for as long as you know or are in possession of material nonpublic information. Remember, anyone scrutinizing your transactions will be doing so after the fact, with the benefit of hindsight. As a practical matter, before engaging in any transaction, you should carefully consider even the appearance of improper insider trading and how enforcement authorities and others might view the transaction in hindsight.

This Insider Trading Policy applies to you and your Affiliated Persons so long as you are associated with the Company. If you leave the Company for any reason, this Insider Trading Policy, including, if applicable, the Trading Procedures described in Part II, will continue to apply to you and your Affiliated Persons until the later of: (1) the first trading day following the public release of earnings for the fiscal quarter in which you leave the Company or (2) the first trading day after any material nonpublic information known to you has become public or is no longer material.

Restricted Trading Periods

From time to time, in connection with an announcement of material information about the Company or when significant developments or announcements are anticipated, we may impose a temporary prohibition on trading in our securities that applies to specified groups of employees or, in rare instances, all persons covered by this policy. In such event, you will be notified by e-mail and/or other means of the imposition and expected duration of the trading prohibition. During that period, no person covered by such a notice may trade in our securities (subject to the limited exceptions set forth in this policy).

C. What is Material Nonpublic Information?

This Insider Trading Policy prohibits you from trading in a company's securities if you are in possession of information about the company that is both "*material*" and "*nonpublic*." If you have a question whether certain information you are aware of is material or has been made public, you should consult with the Compliance Officer.

"Material" Information

Information about our Company or any other company is "material" if it could reasonably be expected to affect the investment decisions of a stockholder or potential investor or if disclosure of the information could reasonably be expected to significantly alter the total mix of information in the marketplace about us or any other company. We speak mostly in this Insider Trading Policy about determining whether information about us is material and nonpublic, but the same analysis applies to information about other companies that would preclude you from trading in their securities.

In simple terms, material information is any type of information that could reasonably be expected to affect the market price of our securities. Both positive and negative information may be material. While it is not possible to identify all information that would be deemed "material," the following items are examples of the types of information that could be material:

- the results of clinical trials, including significant adverse events in a clinical trial or a clinical hold;
- feedback from regulators concerning the design and advancement of clinical trials or requirements for regulatory approval, including the receipt of minutes from any such interactions;
- the timing or expectation of regulatory approval of our product candidates;
- receipt of regulatory designations, such as orphan drug, breakthrough or new chemical entity designations;
- pending or proposed partnering, collaboration and licensing transactions;
- projections of future earnings or losses, or other earnings guidance;
- quarterly financial results that are known but have not been publicly disclosed;
- potential restatements of the Company's financial statements, changes in auditors or auditor notification that the Company may no longer rely on an auditor's audit report;
- pending or proposed corporate mergers, acquisitions, tender offers, joint ventures or dispositions of significant assets;
- changes in senior management or member of our Board of Directors;
- significant actual or threatened litigation or governmental investigations or major developments in such matters;
- cybersecurity risks and incidents, including the discovery of significant vulnerabilities or breaches;
- significant developments regarding products, customers, suppliers, orders, contracts or financing sources (e.g., the acquisition or loss of a contract);
- changes in dividend policy, declarations of stock splits or proposed securities offerings or other financings;
- potential defaults under our credit agreements or indentures or potential material liquidity issues; and
- bankruptcies or receiverships.

The above items will not always be material. For example, some new products or contracts may clearly be material while others may not be. No "bright-line" standard or list of items can adequately address the range of situations that may arise; information and events should be carefully considered in terms of their materiality to the Company.

"Nonpublic" Information

Material information is "nonpublic" if it has not been disseminated in a manner making it available to investors generally.

To demonstrate that information is public, one must be able to point to some fact that establishes that the information has become publicly available, such as the filing of a report with the United States Securities and Exchange Commission (the "SEC"), the distribution of a press release, publishing the information on our website or posting on social media if those are regular ways we communicate with investors, or by other means that are reasonably designed to provide broad public access. Before a person with material nonpublic information can trade, the market must have adequate time to absorb the information that has been disclosed. For the purposes of this Insider Trading Policy, information will be considered public after the completion of one full day of trading following our public release of the information. For that purpose, a full day of trading means a session of regular trading hours on the New York Stock Exchange ("NYSE") or the Nasdaq Stock Market ("Nasdaq") between 9:30 a.m. and 4:00 p.m. Eastern Time (or such earlier closing time as has been set by exchange rules) has occurred.

For example, if the Company publicly discloses material nonpublic information of which you are aware before trading begins on a Tuesday, the first time you can buy or sell Company securities is the opening of the market on Wednesday. However, if the Company publicly discloses material information after trading begins on a Tuesday, the first time that you can buy or sell Company securities is the opening of the market on Thursday.

D. What are the Penalties for Insider Trading and Noncompliance with this Insider Trading Policy?

Both the SEC and the national securities exchanges, through the Financial Industry Regulatory Authority ("FINRA"), investigate and are very effective at detecting insider trading. The U.S. government pursues insider trading violations vigorously, successfully prosecuting, for example, trading by employees in foreign accounts, trading by family members and friends of insiders and trading involving only a small number of shares.

The penalties for violating rules against insider trading can be severe and include:

- forfeiting any profit gained or loss avoided by the trading;
- payment of the loss suffered by the persons who, contemporaneously with the purchase or sale of securities that are subject of a violation, have purchased or sold securities of the same class;
- payment of criminal penalties of up to $5,000,000;
- payment of civil penalties of up to three times the profit made or loss avoided; and

- imprisonment for up to 20 years.

The Company and/or the supervisors of the person engaged in insider trading may also be required to pay civil penalties or fines of $2.5 million or more, up to three times the profit made or loss avoided, as well as criminal penalties of up to $25,000,000, and could under some circumstances be subject to private lawsuits.

Violation of this Insider Trading Policy or any federal or state insider trading laws may subject you to disciplinary action by the Company, including termination of your employment or other relationship with the Company. The Company reserves the right to determine, in its own discretion and on the basis of the information available to it, whether this Insider Trading Policy has been violated. The Company may determine that specific conduct violates this Insider Trading Policy whether or not it also violates the law. It is not necessary for the Company to await the filing or conclusion of a civil or criminal action against an alleged violator before taking disciplinary action.

E. How Do You Report a Violation of this Insider Trading Policy?

If you have a question about this Insider Trading Policy, including whether certain information you are aware of is material or has been made public, you should consult with the Compliance Officer. In addition, if you violate this Insider Trading Policy or any federal or state laws governing insider trading or know of any such violation by any director or employee of the Company, you should report the violation immediately to the Compliance Officer.

PART II. TRADING PROCEDURES

A. Pre-Clearance Procedures

No Insider may trade in our securities, even during an open trading window, unless the trade has been approved by the Compliance Officer in accordance with the procedures described below. In reviewing trading requests, the Compliance Officer may consult with our other officers and/or outside legal counsel and will seek approval of their own trades from the Chief Executive Officer.

1. Procedures. No Insider may trade in our securities unless:

- The Insider has notified the Compliance Officer of the amount and nature of the proposed trade(s) using the Stock Transaction Request form attached to this Insider Trading Policy. To provide adequate time for the preparation of any required reports under Section 16 of the Exchange Act, a Stock Transaction Request form should, if practicable, be received by the Compliance Officer at least two (2) business days before the intended trade date;

- The Insider has certified to the Compliance Officer in writing before the proposed trade(s) that the Insider does not possess material nonpublic information concerning the Company;

- If the Insider is an executive officer or director, the Insider has informed the Compliance Officer, using the Stock Transaction Request form, whether, to the

Insider's best knowledge, (a) the Insider has (or is deemed to have) engaged in any opposite way transactions within the previous six months that were not exempt from Section 16(b) of the Exchange Act and (b) if the transaction involves a sale by an "affiliate" of the Company or of "restricted securities" (as such terms are defined under Rule 144 under the Securities Act of 1933, as amended ("Rule 144")), whether the transaction meets all of the applicable conditions of Rule 144; and

- The Compliance Officer has approved the trade(s) and has certified their approval in writing (which may be by email).

The Compliance Officer does not assume responsibility for, and approval by the Compliance Officer does not protect the Insider from, the consequences of prohibited insider trading.

2. Additional Information.

Insiders shall provide to the Compliance Officer any documentation the Compliance Officer reasonably requires in furtherance of the foregoing procedures. Any failure to provide such information will be grounds for the Compliance Officer to deny approval of the trade request.

3. Notification of Brokers of Insider Status

Insiders who are required to file reports under Section 16 of the Exchange Act shall inform their broker-dealers that (a) the Insider is subject to Section 16; (b) the broker shall confirm that any trade by the Insider or any of their affiliates has been precleared by the Company; and (c) the broker is to provide transaction information to the Insider and/or Compliance Officer on the day of a trade.

4. No Obligation to Approve Trades.

The foregoing approval procedures do not in any way obligate the Compliance Officer to approve any trade. The Compliance Officer has sole discretion to reject any trading request.

From time to time, an event may occur that is material to the Company and is known by only by a limited number of directors and employees. The Compliance Officer may decline an Insider's request to preclear a proposed trade based on the existence of a material nonpublic development – even if the Insider is not aware of that material nonpublic development. If any Insider engages in a trade before a material nonpublic development is disclosed to the public or resolved, the Insider and the Company might be exposed to a charge of insider trading that could be costly and difficult to refute even if the Insider was unaware of the development. So long as the event remains material and nonpublic, the Compliance Officer may decide not to approve any transactions in the Company's securities. The Compliance Officer will subsequently notify the Insider once the material nonpublic development is disclosed to the public or resolved. If an Insider requests preclearance of a trade during the pendency of such an event, the Compliance Officer may reject the trading request without disclosing the reason.

5. Completion of Trades.

After receiving written clearance to engage in a trade signed by the Compliance Officer, an Insider must complete the proposed trade within three (3) business days or make a new trading request. Even if an Insider has received clearance, the Insider may not engage in a trade if (i) such clearance has been rescinded by the Compliance Officer, (ii) the Insider has otherwise received notice that the trading window has closed or (iii) the Insider has or acquires material nonpublic information.

6. Post-Trade Reporting.

The details of any transactions in our securities (including transactions effected pursuant to a Rule 10b5-1 Plan (as defined below)) by an Insider (or an Affiliated Person) who is required to file reports under Section 16 of the Exchange Act must be reported to the Compliance Officer by the Insider or their brokerage firm on the same day on which a trade order is placed or such a transaction otherwise is entered into. The report shall include the date of the transaction, quantity of shares, the price and the name of the broker-dealer that effected the transaction. This reporting requirement may be satisfied by providing (or having the Insider's broker provide) a trade order confirmation to the Compliance Officer if the Compliance Officer receives such information by the required date. Compliance by directors and executive officers with this provision is imperative given the requirement of Section 16 of the Exchange Act that these persons generally report changes in ownership of Company securities within two (2) business days. The sanctions for noncompliance with this reporting deadline include mandatory disclosure in the Company's proxy statement for the next annual meeting of stockholders, as well as possible civil or criminal sanctions for chronic or egregious violators.

B. Exemptions

1. Pre-Approved Rule 10b5-1 Plan.

Transactions made pursuant to an approved Rule 10b5-1 Plan (as defined below) will not be subject to our trading windows or pre-clearance procedures and Insiders are not required to complete a Stock Transaction Request form for such transactions. Rule 10b5-1 of the Exchange Act provides an affirmative defense from insider trading liability under the federal securities laws for trading plans, arrangements or instructions that meet specified requirements. A trading plan, arrangement or instruction that meets the requirements of the SEC's Rule 10b5-1 (a "Rule 10b5-1 Plan") enables Insiders to trade in Company securities outside of our trading windows, even when in possession of material nonpublic information.

The Company has adopted a separate Rule 10b5-1 Trading Plan Policy that sets forth the requirements for putting in place a Rule 10b5-1 Plan with respect to Company securities.

2. Employee Equity and Retirement Plans.

Exercise of Stock Options. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to the exercise for cash of an option to purchase securities of the Company. However, the exercise is subject to the current reporting requirements of Section 16 of the Exchange Act and, therefore, Insiders must comply with the post-trade reporting requirement described in

Section C above for any such transaction. In addition, the securities acquired upon the exercise of an option to purchase Company securities are subject to all of the requirements of this Insider Trading Policy, including the Trading Procedures. Moreover, the Trading Procedures apply to the use of outstanding Company securities to pay part or all of the exercise price of an option, any net option exercise, any exercise of a stock appreciation right, share withholding and any sale of stock as part of a broker-assisted cashless exercise of an option or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

Tax Withholding on Restricted Stock/Units. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to the withholding by the Company of shares of stock upon vesting of restricted stock or upon settlement of restricted stock units to satisfy tax withholding requirements if (a) withholding is required by the applicable plan or award agreement or (b) the election to exercise the tax withholding right was made by the Insider in compliance with the Trading Procedures.

Employee Stock Purchase Plan. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to periodic wage withholding contributions by the Company or its employees that are used to purchase Company stock pursuant to the employees' advance instructions under the Company's 2025 Employee Stock Purchase Plan. However, an Insider may not: (a) elect to participate in the plan or alter their instructions regarding the level of withholding or purchase by the Insider of Company securities under the plan; or (b) make cash contributions to the plan (other than through periodic wage withholding) without complying with the Trading Procedures. Any sale of securities acquired under the plan is subject to the prohibitions and restrictions of the Trading Procedures.

C. Waivers

A waiver of any provision of this Insider Trading Policy or the Trading Procedures may be authorized in writing by a committee of the Board of Directors. All waivers shall be reported to the Board of Directors.

PART III. ACKNOWLEDGEMENT

We will deliver a copy of this Insider Trading Policy to all current employees and directors and to future employees and directors at the start of their employment or relationship with the Company. Each of these individuals must acknowledge that they have received a copy and agree to comply with the terms of this Insider Trading Policy, and, if applicable, the Trading Procedures contained herein. The attached acknowledgment must be completed and submitted to the Company within ten days of receipt.

At our request, directors and employees will be required to re-acknowledge and agree to comply with the Insider Trading Policy (including any amendments or modifications). For that purpose, an individual will be deemed to have acknowledged and agreed to comply with the Insider Trading Policy, as amended from time to time, when copies of those items have been delivered by regular or electronic mail (or other delivery option used by the Company) to the Compliance Officer.

* * *

Questions regarding this Insider Trading Policy are encouraged and may be directed to the Compliance Officer.

EFFECTIVE: January 8, 2026

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-292679 on Form S-8 of our report dated March 30, 2026, relating to the financial statements of Aktis Oncology, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

March 30, 2026

Exhibit 31.1

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

I, Matthew Roden, certify that:

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

Date: March 30, 2026

/s/Matthew Roden
Matthew Roden
President and Chief Executive Officer

Exhibit 31.2

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

I, Kyle D. Kuvalanka, certify that:

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

Date: March 30, 2026

/s/Kyle D. Kuvalanka
Kyle D. Kuvalanka
Chief Financial Officer

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Aktis Oncology, Inc. (the "Company") for the fiscal year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2026

By: /s/ Matthew Roden

Matthew Roden, PhD
Chief Executive Officer
(Principal Executive Officer)

Date: March 30, 2026

By: /s/ Kyle D. Kuvalanka

Kyle D. Kuvalanka
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 97.1

AKTIS ONCOLGY, INC.

COMPENSATION RECOVERY POLICY

EFFECTIVE JANUARY 8, 2026

Aktis Oncology, Inc., a Delaware corporation (the "Company"), has adopted a Compensation Recovery Policy (this "Policy") as described below.

1. Overview

This Policy sets forth the circumstances and procedures under which the Company shall recover Erroneously Awarded Compensation from Covered Persons (as defined below) in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Nasdaq Stock Market. Capitalized terms used and not otherwise defined herein shall have the meanings given in Section 3 below.

2. Compensation Recovery Requirement

In the event the Company is required to prepare a Financial Restatement, the Company shall recover reasonably promptly all Erroneously Awarded Compensation with respect to such Financial Restatement.

3. Definitions

a. "Applicable Recovery Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to 12 months will be deemed to be a completed fiscal year.

b. "Applicable Rules" means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

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

d. "Committee" means the Compensation Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the Board.

e. "Covered Person" means any Executive Officer and any other person designated by the Board or the Committee as being subject to this Policy. A person's status as a

Covered Person with respect to Erroneously Awarded Compensation shall be determined as of the time of receipt of such Erroneously Awarded Compensation regardless of the person's current role or status with the Company (e.g., if a person began service as an Executive Officer after the beginning of an Applicable Recovery Period, that person would not be considered a Covered Person with respect to Erroneously Awarded Compensation received before the person began service as an Executive Officer, but would be considered a Covered Person with respect to Erroneously Awarded Compensation received after the person began service as an Executive Officer where such person served as an Executive Officer at any time during the performance period for such Erroneously Awarded Compensation).

f. "Effective Date" means the date of effectiveness of the Company's S-1 registration statement.

g. "Erroneously Awarded Compensation" means the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date and during the Applicable Recovery Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in a Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Compensation with respect to Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules. Incentive-Based Compensation is deemed received, earned or vested when the Financial Reporting Measure is attained, not when the actual payment, grant or vesting occurs.

h. "Exchange" means the Nasdaq Stock Market LLC.

i. An "Executive Officer" means any person who served the Company in any of the following roles at any time during the performance period applicable to Incentive-Based Compensation and received Incentive-Based Compensation after beginning service in any such role (regardless of whether such Incentive-Based Compensation was received during or after such person's service in such role): the president, principal financial officer, principal accounting officer (or if there is no such accounting officer the controller), any vice president in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy making function or any other person who performs similar policy making functions for the Company. Executive officers of parents or subsidiaries of the Company may be deemed executive officers of the Company if they perform such policy making functions for the Company.

j. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

k. "Incentive-Based Compensation" means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure and any other equity-based compensation provided by the Company or any of its subsidiaries, including, without limitation, stock options, restricted stock awards, restricted stock units and stock appreciation rights.

l. A "Financial Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

m. "Restatement Date" means, with respect to a Financial Restatement, the earlier to occur of: (i) the date the Board concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

6. Tax Considerations

To the extent that, pursuant to this Policy, the Company is entitled to recover any Erroneously Awarded Compensation that is received by a Covered Person, the gross amount received (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned by the Covered Person.

7. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Compensation hereunder, which may include, without limitation, any one or more of the following:

a. requiring reimbursement of cash Incentive-Based Compensation previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards;

c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;

d. adjusting or withholding from unpaid compensation or other set-off;

e. cancelling or offsetting against planned future grants of equity-based awards; and/or

f. any other method permitted by applicable law or contract.

Notwithstanding the foregoing, a Covered Person will be deemed to have satisfied such person's obligation to return Erroneously Awarded Compensation to the Company if such Erroneously Awarded Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

8. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining whether a financial restatement qualifies as a Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances besides those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules.

9. Policy Administration

This Policy shall be administered by the Committee; provided, however, that the Board shall have exclusive authority to authorize the Company to prepare a Financial Restatement. In doing so, the Board may rely on a recommendation of the Audit Committee of the Board. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of this Policy that the

Committee deems to be necessary or appropriate to the administration of this Policy. The interpretation and construction by the Committee of any provision of this Policy and all determinations made by the Committee under this policy shall be final, binding and conclusive.

10. Compensation Recovery Repayments not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Compensation or for any losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Policy.