Filed Pursuant to Rule 424(b)(3)
Registration Statement No. 333-284569

Prospectus Supplement No. 2
(To Prospectus Dated February 4, 2025)

Kairos Pharma, Ltd.

2,500,000 shares of Common Stock Issuable Upon Exercise of the Pre-Funded Warrants
3,750,000 shares of Common Stock Issuable Upon Exercise of the Common Warrants
175,000 shares of Common Stock Issuable Upon Exercise of the Placement Agent Warrants

This prospectus supplement No. 2 updates, amends and supplements the prospectus dated February 4, 2025 (as supplemented or amended from time to time, the "Prospectus"), which forms a part of our Registration Statement on Form S-1, as amended (Registration No. 333-284569).

This prospectus supplement is being filed to update, amend and supplement the information in the Prospectus with the information contained in our Annual Report on Form 10-K for the fiscal year ended December 31, 2025, originally filed with the Securities and Exchange Commission on March 31, 2026 (the "Annual Report"). Accordingly, we have attached the Annual Report to this prospectus supplement.

The Prospectus relates to the offer for sale of an aggregate of 6,425,000 shares of common stock, par value $0.001 per share ("common stock"), of Kairos Pharma, Ltd. (the "Company"), consisting of (i) 2,500,000 shares of common stock underlying the pre-funded warrants, exercisable for $0.001 per share, and (ii) 3,750,000 shares of common stock underlying common stock purchase warrants, each exercisable for $1.40 per share, all of which were issued to the investor in a private placement offering which closed on January 16, 2025 (the "PIPE Offering"). In addition, we are registering 175,000 shares of common stock, exercisable at $1.40 per share, underlying common stock purchase warrants issued to Boustead Securities, LLC and D. Boral Capital LLC as compensation for their services as co-placement agents for the PIPE Offering.

You should read this prospectus supplement in conjunction with the Prospectus, including any amendments or supplements to it. This prospectus supplement is qualified by reference to the Prospectus, except to the extent that the information provided by this prospectus supplement supersedes information contained in the Prospectus. This prospectus supplement is not complete without and may not be delivered or used except in conjunction with, the Prospectus, including any amendments or supplements to it. You should keep this prospectus supplement with your Prospectus for future reference.

Our common stock is listed on NYSE American under the symbol "KAPA." On March 31, 2026, the last reported sale price of our common stock was $0.559 per share. We recommend that you obtain current market quotations for our common stock prior to making an investment decision.

We are an "emerging growth company" under federal securities laws and are subject to reduced public company reporting requirements. Investing in our securities involves a high degree of risk. See the section entitled "Risk Factors" beginning on page 11 of the Prospectus, and under similar headings in any amendments or supplements to the Prospectus, and beginning on page 25 of our Annual Report on Form 10-K contained herein.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 1, 2026.

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ANNUAL REPORT ON FORM 10-K FOR THE FISCAL YEAR ENDED DECEMBER 31, 2025

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **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: 001-42275

KAIROS PHARMA, LTD.
(Exact name of registrant as specified in its charter)

Delaware	**46-2993314**
(State or other jurisdiction of incorporation or organization)	(I.R.S Employer Identification No.)

2355 Westwood Blvd., #139
Los Angeles CA 90064
(Address of principal executive offices) (Zip Code)

(310) 948-2356
(Registrant's telephone number, including area code)

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 $0.001 per share	KAPA	NYSE American

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 Section 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, a 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 Act). Yes ☐ No ☒

At June 30, 2025, the last day of the Registrant's most recently completed second fiscal quarter, the aggregate market value of Registrant's common shares held by non-affiliates was approximately $6.9 million based upon the closing sale price as reported on the NYSE American. This calculation of market value has been made

for the purposes of this report only and should not be considered as an admission or conclusion by the Registrant that any person is in fact an affiliate of the Registrant.

As of March 31, 2026, the Registrant had 21,411,198 shares of Common Stock outstanding.

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PART I

Disclosure Regarding Forward-Looking Statements

This Annual Report on Form 10-K (the "Annual Report") contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and such forward-looking statements involve risks and uncertainties. Statements about our future results of operations and financial position, business strategy, product candidates, planned preclinical and nonclinical studies and clinical trials, results of preclinical and nonclinical studies, clinical trials, research and development costs, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and 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.

Words such as "could," "may," "will," "should," "likely," "anticipates," "expects," "intends," "plans," "projects," "believes," "estimates," and variations on such words, including similar expressions, are used to identify these forward-looking statements. Forward-looking statements contained in this Annual Report include, but are not limited to, statements about:

- the initiation, timing, progress and results of our preclinical and nonclinical studies and clinical trials, and our research and development programs, including the manufacture of clinical trial material and drug product for launch;
- our ability to successfully complete our ongoing and planned for clinical trials and obtain regulatory approval in the United States for our target drugs;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals as needed;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the ability to commercialize our product candidates, if approved;
- the ability of our current in-development products, if approved, to successfully compete with other therapies, including therapies currently in development;
- the pricing, coverage and reimbursement of our product candidates, if approved;
- the implementation of our business model, strategic plans for our business, and product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- our ability to identify additional product candidates and advance them into clinical development;
- our estimates regarding expenses, capital requirements and needs for additional financing;
- our financial performance; and
- developments relating to our competitors and our industry.

These risks and uncertainties, all of which are difficult or impossible to predict accurately and many of which are beyond our control, include, but are not limited to those made below under "Summary of Risk Factors" and in Item 1A. Risk Factors in this Annual Report. You should carefully consider these risks, as well as the additional risks described in other documents we file with the Securities and Exchange Commission ("SEC"). We also operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all such risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements.

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. Forward-looking statements in this Annual Report are based on management's current views and assumptions regarding future events and speak only as of the date when made. Kairos undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by federal securities laws.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

Unless otherwise necessary or appropriate in the context, references in this Annual Report to "Kairos," the "Company," "we," "us," and "our" refer to Kairos Pharma, Ltd., a Delaware corporation, and our wholly owned subsidiary, Enviro Therapeutics, Inc., a California corporation.

ITEM 1. BUSINESS

Overview

We are a clinical-stage biopharmaceutical company advancing therapeutics for cancer patients that are designed to overcome key hurdles in immune suppression and drug resistance. These therapeutics include antibodies and small molecules for the treatment of prostate cancer, lung cancer, breast cancer, and glioblastoma. We are driven by innovative science to develop novel and transformative drug therapies to treat cancer.

Our mission is to advance our portfolio of innovative therapeutics to target key mechanisms of therapeutic resistance and immune suppression and transform the way cancer is treated. We have leveraged molecular insights of the mechanisms of therapeutic resistance and immune suppression to develop a new class of novel drugs that we expect will target drug resistance and checkpoints of immune suppression. Our seven-drug portfolio offers diversification and mitigates the overall exposure to many of the inherent risks of drug development. Our proprietary technologies are licensed from Cedars-Sinai Medical Center, the largest academic medical center in the Western U.S. and ranked number one in California and number two in the nation in U.S. News & World Report's Best Hospitals Honor Roll for 2022-2023. As of the date of this Annual Report, our product candidates have not been approved as safe or effective by the FDA or any other comparable foreign regulator.

Our product portfolio currently consists of:

- Five pre-clinical or clinical-trial stage drug candidates developed by us and designed to target immune response.
- Two therapeutic agents developed by our Enviro Therapeutics, Inc. subsidiary and designed to increase anti-tumor response in conjunction with cancer therapies by addressing resistance to these agents.
- A variety of technologies licensed by our Enviro Therapeutics, Inc. subsidiary and consisting of compositions and methods for treating diseases and conditions by targeting CD105 and depleting mitochondrial DNA from the circulation.

Our Science

The human immune system can tell the difference between normal cells in the body and those it sees as "foreign," which allows it to focus an attack on the foreign cells while leaving the normal cells alone. To do this, our immune system uses "checkpoints" - molecules on certain immune cells that need to be activated (or inactivated) to start an immune response. Cancer cells can find ways to use these checkpoints to avoid being attacked by the immune system.

We are developing small molecules that we believe can specifically target these central checkpoints. In addition, we are developing an activated T cell therapy designed to target cancer stem cells.

In June of 2021, we announced the acquisition of Enviro Therapeutics, Inc. to incorporate their advanced pipeline of drug candidates in Phase 1 and Phase 2 trials. The pipeline includes two therapeutic agents addressing what we believe to be significant unmet needs in prostate and lung cancer markets and that we believe can help address cancer progression, in particular, in those cancers that develop resistance to standard therapies.

As a result, we have a pipeline of seven drugs. We have filed an Investigational New Drug, or IND, application with the FDA that has become effective for ENV 105. As a result, we began a Phase 1 trial for non-small cell lung cancer in September 2023 and in September 2023 opened a randomized Phase 2 trial for prostate cancer. We believe that the mechanism of action for ENV 105 may addresses the resistance mechanism of tumor dormancy. This was only possible because ENV 105 targets both the cancer cells as well as its supportive non-cancer environment. The advantage of targeting the unique environment supporting the tumor cells is that their capacity to adapt and evade therapy is significantly lower than that of the cancer itself. As such, ENV 105 is designed to address resistance to chemotherapy, radiation therapy, androgen targeted therapy, EGFR inhibitors, or checkpoint inhibition when given in combination. Interestingly, since the target of ENV 105, endoglin, is upregulated by the tumor and supporting cells in response to androgen targeted therapy and EGFR inhibitors as a proven mechanism of resistance, we believe the co-administration of ENV 105 specifically targets this mechanism of resistance.

Through the Enviro Therapeutics, Inc. acquisition, we also obtained ENV 205, a pre-clinical therapeutic for treating diseases and conditions by depletion of mitochondrial DNA from circulation and for detection of mitochondrial DNA. We intend to use this antibody technology to treat chemotherapy resistance and for cachexia, a common problem in the cancer patient population.

Our Pipeline

We have sought to develop a broad portfolio of novel and transformative drug therapies to treat cancer. Our current portfolio consists of seven drug therapies consisting of peptide and small molecule cancer immunotherapeutics KROS 101, 102, 201, 301 and 401 and therapeutic agents ENV 105 and 205. We started three clinical trials in the fall of 2023 for KROS 201 and ENV 105.

KROS 101 is a small molecule that targets the GITR ligand, a signal for T cell growth to remove a checkpoint barrier to fight a host of cancers. Our second drug, KROS 201, is a T cell therapy activated by dendritic cells to treat glioblastoma, a deadly and common brain cancer. Our ENV 105 drug seeks to address unmet medical needs in large markets of prostate and lung cancers. For example, the global prostate cancer therapeutics market size was valued at USD 7.9 billion and at USD 1.7 billion for EGFR mutant non-small cell lung cancer. Our ENV 105 biologic drug targets endoglin and addresses resistance to androgen targeted drugs and EGFR inhibitors. A Phase 2 trial involving a heavily pre-treated population suffering from prostate cancer was initiated at Cedars-Sinai Medical Center. The primary objective of the study was to measure the proportion of patients at two months who had either disease stabilization or regression (i.e. complete or partial response), referred to as the clinical benefit rate. A clinical benefit rate of 62% was observed. This Phase 2 trial involved the use of enzalutamide (Xtandi®, Pfizer) and abiraterone (ZYTIGA®, Janssen), two forms of hormone therapy that blocks the androgen receptor and its target ligand, testosterone, respectively. These two agents are considered standard of care for nearly all recurrent prostate cancer patients.

The trial accrued patients that were resistant to the very androgen targeted therapy (enzalutamide or abiraterone) that was given in the trial in addition to ENV105. Importantly, ENV105 administration alone has no clinical benefit, based on pre-clinical findings (conducted by us) and previous clinical findings (through trials performed by the National Cancer Institute). However, two agents that apparently have no clinical effect, when combined result in halting tumor progression. The finding is well justified by numerous publications demonstrating hormone therapy resistance develops through the induction of CD105, the target of ENV 105 [Placencio-Hickok et al. (2020) Endocrine Related Cancer 27:1; Kato et al. (2020) Oncogene 38: 716; Smith et. al. (2023) Molecular Therapy 31: 78; Thiruvalluvanet. al. (2023) Cancers 14: 2491]. All the patients in the trial were not only resistant to the two hormone therapy agents, but the patients had all had at least one other intervention after surgical or radiation progression. For some they had failed to respond to five other drugs. The responders to the combination therapy were patients that had exceedingly few other options for survival. The study enrolled 11 patients prior to closure, each of whom were enrolled in one of two arms (or specific treatments) in the clinical trial. Three patients were enrolled in the abiraterone acetate arm and eight in the enzalutamide arm. Of these patients only two and six patients on each arm were considered assessable, respectively (i.e. completed at least two months of therapy with imaging). Of the 11 patients enrolled in the trials, nine were evaluable. This investigator-initiated trial closed to accrual prior to its planned enrollment of 40 patients due to limitation of the drug supply from the manufacturer. The drug supply has since been expanded and obtained by Kairos Pharma. The primary objective of the study was to measure the proportion of patients at two months who had either disease stabilization or regression (i.e., complete or partial response), referred to as the clinical benefit rate. Disease status assessments were made by RECIST 1.1 or PCWG3 criteria. One of the two patients on the abiraterone arm experienced a <50% decline in his serum PSA concentration with disease stabilization by scans. Four of the six patients on the enzalutamide arm experienced clinical benefit by three showing stabilization of disease, and one showing decline in his serum PSA concentration and scan improvement. Grade 3 side effects consisting of hyponatremia, urinary retention, and cellulitis were noted on the abiraterone arm. None of these grade 3 events were attributed to the use of ENV105. No grade 3 events were noted on the enzalutamide arm. The most frequent grade 1-2 events occurring in at least two patients included anemia, nausea, and gingival bleeding.

A three-gene panel was identified to serve as a companion biomarker for patient selection. There are no approved companion diagnostic tests for ENV105. However, candidate biomarkers revealed in the previous Phase 2 trial will be verified in the new Phase 2 trial to better predict patients that would best respond to the ENV105. Our Enviro Therapeutics, Inc. subsidiary will strive to co-develop companion biomarkers with all drugs in its portfolio, enabling identification of potential drug responders prior to therapy. As of the date of this Annual Report, our companion diagnostics are in development and have not been approved by the FDA. There is no guarantee that these companion diagnostics will be approved by the FDA or comparable foreign regulatory agencies.

On May 21, 2024, the NIH announced that it was awarding Neil Bhowmick, PhD, our Chief Scientific Officer and also a Cedars-Sinai Professor of Medicine, a grant of $3.2 million to support the development of the mechanism of action and companion biomarkers in research that is being performed by Cedars-Sinai in conjunction with our ongoing Phase 2 trial for ENV105 (carotuximab) and apalutamide treating castrate resistant prostate cancer patients. This funding will be used by Cedars-Sinai, through Dr. Bhowmick's study, to test for the biomarkers and genetic studies corollary studies to support our ongoing Phase 2 trial for ENV105, and also to help identify biomarker positive patients who will potentially respond to ENV105 in a future Phase 3 trial. This supporting work is being carried out by Cedars-Sinai, through Dr. Bhowmick's laboratory. These corollary studies will not offset the costs of the clinical trial that Kairos anticipates expending. The NIH funding will be dispersed to Cedars-Sinai and Dr. Bhowmick in stages during the Phase 2 trial for ENV105. The NIH grant does not otherwise change the cost or management of the ongoing Phase 2 clinical trial.

KROS 101 is a small molecule that induces trimerization of the GITR ligand and is the culmination of the pioneering work of Dr. Ramachandran Murali, our Vice President of Research and Development, in 3D crystallography. KROS 201 consists of potent T cells that are stimulated by dendritic cells in the test tube to target cancer stem cells. Our initial focus of KROS 201 is to treat glioblastoma. Dr. Yu runs a lab that is known for its pioneering work in dendritic cell immunotherapy.

ENV 105 demonstrated an ability to target CD105 which is elevated in drug resistance in prostate cancer. Androgen therapy resistance in prostate cancer is being targeted in the Phase 2 trial. EGFR antagonist resistance in lung cancer is being targeted in a Phase 1 trial. The ENV 105 Phase 2 trial in prostate cancer with apalutamide (Janssen) is a multicenter trial being conducted at Cedars-Sinai, University of Utah, and City of Hope. The Phase 1 trial in lung cancer with Tagrisso (AstraZeneca) is being conducted at Cedars-Sinai.

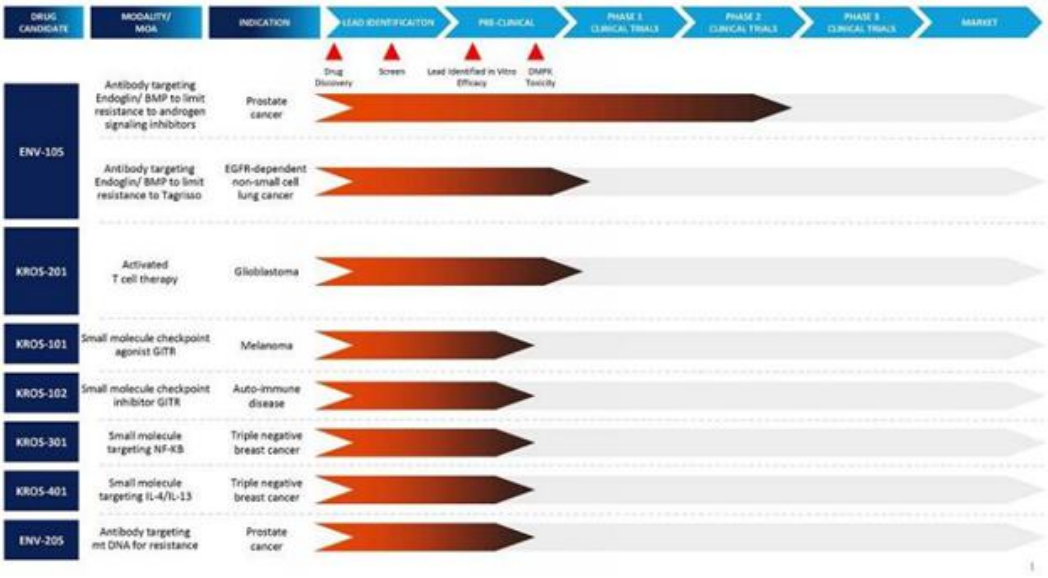
We are also developing KROS 102, KROS 301, and KROS 401. KROS 102 is a GITR ligand antagonist designed to increase inhibitory Treg functions while hampering T effector cell numbers and function. KROS 301 is a tumor targeting small molecule and checkpoint inhibitor with two distinct mechanisms of action resulting from blocking intranuclear localization of RelA, a key component of the NF-KB pathway. KROS 401 is a tumor microenvironment immune modulator and cyclic peptide inhibitor of IL-4 and IL-13 reversing tumor associated macrophage inhibition. Both therapies reverse the mechanism of immune suppression at the tumor site.

Finally, we are developing ENV 205, what we believe to be a first-of-its-kind biologic that targets prostate cancers that have become otherwise resistant to chemotherapy. As of the date of this Annual Report, ENV 205 has not been approved by the FDA or any other comparable foreign regulator. ENV 205 targets the excretion of mitochondrial DNA found elevated in circulation when patients are on chemotherapy. Higher blood levels of mitochondrial DNA are not only associated with chemotherapy resistance, but more widely recognized as a mediator of cardiac toxicity and other systemic inflammatory events contributing to the negative side effects of chemotherapy use. Thus, depleting mitochondrial DNA with the administration of ENV 205 restores chemotherapy sensitivity with reduced toxic side effects.

Addressing these critical targets strike cancer at what we believe to be its most vulnerable point. The group of founding scientists generating our initial drugs have combined their pioneering contributions in structural, biology, immunology, and cancer therapy to bring to unmet medical needs what we believe are life changing therapeutics. As of the date of this Annual Report, aside from the clinical trials, which are conducted off-site at third party facilities, our operations are all conducted virtually as we aim to be efficient in our deployment of capital and leverage our history with premier academic medical centers to efficiently enroll and execute clinical trials.

Our Development Pipeline and Programs

Our drug development programs for KROS 101, 102, 201, 301, and 401 as well as therapeutic agents ENV 105 and ENV 205 are summarized in the following table.



Kairos-Developed Products

Kairos' products consist of five pre-clinical or clinical-trial stage drug candidates developed by Kairos and designed to target immune response.

KROS 101 is an orally available GITR (glucocorticoid-induced tumor necrosis factor receptor) ligand small-molecule antagonist designed to deplete regulatory T cells (Tregs) and activate effector T cells to augment the antitumor immune response for the treatment of patients with cancer. We are developing KROS 101 as a systemic immune modulator to address immunosuppressive activity of solid cancers and we are currently working towards completing IND-enabling pharmacokinetic, toxicity and safety studies in 2024 . KROS 101 stabilizes the GITR ligand to signal GITR to impact cancer therapy. GITR is a powerful checkpoint that suppresses the immune response against cancer. This checkpoint is a central switch that promotes "killer" effector T cell functions and hampers inhibitory regulatory T cell (Treg) functions. Due to its central role in regulating Treg, GITR receptor complex is considered an optimal therapeutic target for treating cancer. This may be the optimal complement to add to current checkpoint inhibitors as it shows a dose dependent effective response in increasing the immune response. As a competitive antagonist, KROS 101 could be dosed to avoid the typical common side effects of checkpoint inhibitors.

We believe our GITR targeting small molecule has the potential to be a significant improvement over existing antibody treatments that have been tested in clinical trials. When GITRL binds to the GITR on the surface of Treg cells, the suppressive activity of Treg cells against effector T cells is reduced. While on the effector T cell, GITR-GITRL binding induces the proliferation of effector T cells. This receptor is central to the regulation of the immune system.

Whereas previous competitor therapeutics targeting GITR were antibodies that bind the receptor, our small molecule drug fits into the GITR ligand stabilizing the three-pronged trimer structure. This structure enables the amplification of the GITR receptor trimer, leading to physiologic signaling for T cell proliferation. The analogy is a digital signal rather than a limited analog signal. This powerful physiologic signal can lead to exponential signaling of T cells to proliferate against cancer cells. In addition, the small molecule half-life enables reversibility, allows for fine tuning to limit side effects. Having both agonist and antagonist molecules can reverse potential untoward effects. In addition, this small molecule may also be given orally as a medication. The discovery of KROS 101 was the culmination of transformative structural biology based on exclusive proprietary 3D crystallography first used to model GITR ligand by Kairos' scientists.

KROS 101 is currently in pre-IND studies in development for a Phase 1 trial.

KROS 102 is a GITR antagonist designed to increase the inhibitory regulatory T cell (Treg) functions, while hampering T effector cell numbers and function. KROS 102 has been shown to decrease T effector cells and increase Treg cells in a dose dependent fashion to treat autoimmune diseases. We are developing a novel GITR inhibitor that can impact the abnormal immune responses against one's own body.

Due to its central role in regulating Treg, the GITR receptor complex is an optimal therapeutic target to treat autoimmunity. By potently and specifically inhibiting an immune response, this strategy may impact autoimmune diseases such as Crohn's disease, multiple sclerosis, and rheumatoid arthritis. KROS 102 has been shown to decrease T effector cells and increase Treg cells in a dose dependent fashion. KROS 102 is currently in preclinical studies.

KROS 201 is a proprietary technology for the production of activated T cells. Activated T cells (ATC) are killer T cells that are made from a patient's white blood cells in a cell culture by activating with cytokines or T cell activating signals and by priming dendritic cells loaded with glioblastoma cancer stem cell specific antigens. Kairos generates activated T cells that will be infused intravenously into patients with recurrent glioblastoma.

KROS 201 begins with the activation of T cells using dendritic cells for the treatment of patients with glioblastoma. Activated T cells (ATC) are killer T cells that are made from a patient's white blood cells in a cell culture by activating with cytokines or T cell activating signals and by priming dendritic cells loaded with glioblastoma cancer stem cell specific antigens. Cytotoxic and helper T cells are generated in a cell manufacturing center and infused into patients with recurrent glioblastoma.

We believe KROS 201 has the potential to become a novel T cell therapy that allows a "plug and play" scenario where a patient's specific tumor can be addressed as well as the improvement of cancer treatment by stimulating patients' immune systems to generate a long-term population of cytotoxic T cells & helper T cells directed against the tumor.

We completed IND-enabling pharmacology and toxicology studies and submitted an IND application.

KROS 301 is a tumor-targeting small molecule and checkpoint inhibitor with two distinct mechanisms of action resulting from blocking intranuclear localization of RelA, a key component of the NF-KB pathway. NF-KB is a key component for cancer growth and drug resistance. KROS 301 targets tumor cells in in RelA/p65 biomarker positive solid tumors. The use of this biomarker enables choosing patients that will respond to the drug enabling efficient clinical trials that are more likely to succeed. KROS 301 is in active pre-clinical development. Separate approval will be required for the development and approval of a companion diagnostic. This approval may be delayed or not issued by the FDA.

KROS 401 is a tumor microenvironment immune modulator and cyclic peptide inhibitor of IL-4 and IL-13 reversing tumor associated macrophage inhibition. KROS 401 reduced the M2 macrophage population and limits fibrosis of the pancreas due to anti-inflammatory process (Xue, Nature Com. 2015). Other indications may include pulmonary fibrosis, Crohn's disease, and other inflammatory conditions. KROS 401 blocks the IL4/IL13 cytokine immune receptors for triple negative breast cancer and in addition, it increases anti-tumor response in conjunction with radiation therapy in an animal model.

Recently, it became clear that macrophages in tumors are altered by the Th2 cytokines IL-4 and IL-13, inducing alternatively activated macrophages or M2. Breast cancer associated tumor associated macrophages are mainly activated M2 macrophages. Thus, shifting the balance toward M1 macrophages will prevent tumor growth and enable T cell activation and killing, which is dependent on Th1 cytokines. We will target a key Th2 cytokine pathway, IL-4, and IL-13 to block macrophage immunosuppression with KROS 401, thereby allowing T cells to access tumors.

We believe there are significant advantages to KROS 401 as our peptide binds to IL13R alpha1 and IL4R alpha1 (type I) receptor complex and blocks both IL-4 and IL-13 mediated signaling. The implication is that targeting IL-4Ralpha is predominantly for indications such as asthma or eczema, while the type I is for macrophages/tumor growth (esp IL13R). KROS 401 is in preclinical development.

Enviro and Enviro-Licensed or -Acquired Products

Enviro's product portfolio includes two therapeutic agents at different stages of clinical development.

ENV 105 is a Phase 2 clinical stage therapeutic agent designed to address cancer progression. ENV 105 is an antibody therapeutic designed for use by prostate cancer patients resistant to androgen-targeted therapy, which is being tested in a Phase 2 clinical trial. We began accruing patients for the trial in September 2023. This multicenter randomized Phase 2 trial involving Cedars-Sinai Medical Center and City of Hope in Los Angeles California and Huntsman Cancer Center in Utah is testing the combination of a third-generation androgen targeted therapy, apalutamide (Janssen), with or without ENV 105 for prostate cancer patients that have developed resistance to at least one other androgen targeted inhibitor (NCT05534646). Dr. Edwin Posadas is the principal investigator of this multi-institutional trial. Dr. Posadas is Director of the Experimental Therapeutics Program and the Medical Director of the Urologic Oncology Program at the Samuel Oschin Comprehensive Cancer Institute at Cedars-Sinai Medical Center. Companion biomarkers for efficient selection of patients to potentially respond to the drug will be evaluated in this trial. The genetic biomarker potentially identifies responsive patients to ENV 105 prior to therapy for a future Phase 3 trial. The companion biomarker would require a separate approval by the FDA. Prostate cancer is the most common, non-cutaneous cancer affecting men in the United States and 1.2 million new cases registered worldwide. It is also the second leading cause of cancer death in American males. Androgen targeted therapy accounts for USD 15 billion in sales in 8 primary markets. Since nearly all patients eventually develop resistance to androgen targeted therapy, addressing this population with a drug targeting endoglin (ENV 105) is of high value for this single indication. In clinical trials, ENV 105 has been shown to be reasonably well-tolerated in patients as an adjunct to contemporary androgen targeted inhibitors (NCT03418324). Grade 3 hyponatremia, urinary retention, and cellulitis were noted on the abiraterone arm. None of these were attributed to the use of ENV105. No grade 3 events were noted on the enzalutamide arm. The most frequent grade 1-2 events occurring in at least two patients (listed as abiraterone, enzalutamide) included anemia, nausea, and gingival bleeding. Careful mechanism-of-action studies have revealed that ENV 105 impacts a more ubiquitous means of cancer drug resistance, cancer dormancy, the growth potential for this drug alone can be large. A Phase 1 EGFR antagonist resistant non-small cell lung cancer targeted therapy combination of Tagrisso (osimertinib, AstraZeneca) and ENV 105 is at Cedars-Sinai Medical Center. The principal investigator of this clinical trial is Dr. Karen L. Reckamp, Professor in Medicine, Director of the Division of Medical Oncology at Cedars-Sinai Medical Center. We also expect targeted therapies to contribute to the growth of the prostate and EGFR-dependent non-small cell lung cancer market, as immune therapies have not shown efficacy for these two cancer types.

ENV 205, an antibody fragment targeting mitochondrial DNA was shown to limit chemotherapy resistant prostate cancer in preclinical studies. Mitochondrial DNA depletion limit inflammation-induced pro-tumorigenic activity and sensitizes prostate cancer to docetaxel. This biologic is a first of its kind strategy of chemotherapy sensitization. The development of chemotherapy resistance is an unfortunate eventuality for patients with solid tumors. ENV 205 has been shown to particularly sensitize tumors to docetaxel, a taxane class of chemotherapy. Docetaxel is used to treat several cancers such as stomach cancer, breast cancer, non-small-cell lung cancer, prostate, and head and neck cancer. Apart from restoring efficacy of docetaxel in certain resistant tumors, the use of ENV 205 allows for reduced dosing of the chemotherapy required to achieve the same tumor cell killing. This is paradigm shifting in patient quality of life, limiting the significant side-effects of chemotherapy. According to Business Research Insights, docetaxel market size $137 billion globally in 2024, and is expected to reach $329 billion by 2033.

Our Market Opportunity

Global cancer drug spending was valued at approximately $232 billion in 2024, and is expected to reach some $532 billion by 2031 driven largely by the growth of targeted therapies and immuno-oncology (https://www.biospace.com/oncology-drugs-market-to-reach-usd-532-91-billion-by-2031-coherent-market-insights#:~:text=The%20global%20Oncology%20Drugs%20Market,report%20by%20Coherent%20Market%20Insights.). Global immunotherapy market was valued at $226 billion by 2024 and is projected to grow at a CAGR of 11.9% from 2025 to 2030 (Grand View Research). Increasing patient pool and higher mortality rates are augmenting the need for cancer immunotherapy globally. We are uniquely positioned to advance our immunotherapies that may have the potential to transform the way cancer is treated using antibodies that target CD105 to reverse drug resistance to prostate and lung cancer and activated T cells that target cancer stem cells that are the root of glioblastoma. Our pipeline of immunotherapeutic agents that signals growth of effector T cells against cancer, and reverse immunosuppression at the cancer site are being rapidly advanced to address large unmet needs in cancer immunotherapy.

ENV 105

The broad application of ENV 105 as a complementary drug to support standard of care cancer therapy for many cancer types has revealed numerous potential therapeutic strategies that have not been exhaustively explored in pre-clinical models. This is based on the identification that ENV 105 acts on both the cancer cells and cancer associated fibroblastic cells, thus it complements many cancer epithelia-directed therapies. However, we have focused on three indications in pre-clinical studies, two of which have matured to clinical trials: prostate cancer (Phase 2 with androgen signaling inhibitors), lung cancer (Phase 1 with EGFR antagonist), and head and neck cancer (preclinical with radiation or chemotherapy).

Prostate cancer: There are some 300,000 castrate resistant prostate cancer patients in the U.S. eligible to be given combination therapy of ENV 105 + androgen signaling inhibitors for $5,000 per month (based on comparable neutralizing antibodies). This would suggest a potential US$9 billion gross sales for ENV 105 for a six-month dose in the U.S. for this single indication. As a point of reference, androgen signaling inhibitors on their own make up $10 billion market inclusive of Sanofi; Johnson and Johnson Services, Inc.; Pfizer, Inc.; Astellas Pharma, Inc.; and Bayer AG - predicted to grow to $15 billion global market by 2027 of castrate resistant prostate cancer patients. None have been approved to extend efficacy apart from chemotherapy (docetaxel and cabazitaxel) with undesirable toxicity profiles.

Lung cancer: There are approximately 30,466 patients with an EGFR driven non-small cell lung cancer annually in the U.S. The incidence of EGFR driven NSCLC is most prevalent in non-smokers and those of east Asian descent, 35-40% of NSCLC - 341,633 patients annually in Asia (China, India, Japan, S. Korea, Thailand, Philippines). To determine lung cancer market share for ENV 105, the current market share for Tagrisso (US$3 billion annual sales for AstraZeneca) can be used as point of reference. Accordingly, ENV 105 could have a $1 billion market share in the U.S. as a combination therapy with EGFR antagonists to improve or extend its efficacy.

Head and neck cancer: The capacity for ENV105 to complement both radiation and chemotherapy would suggest future clinical application in many solid tumor types. For head and neck cancer, the World Health Organization estimates more than 550,000 new cases of and around 300,000 deaths per year. The rising consumption of alcohol and tobacco is a major factor behind estimated 7.9% increase in the head and neck cancer by 2030. The global head & neck cancer drug market is estimated to reach $8.1 billion in 2031. (See https://www.ihealthcareanalyst.com/global-head-neck-squamous-cell-carcinoma-drugs-market/). Chemotherapy is the standard of care alone or in combination with radiation therapy, where toxicity is the greatest limitation. Administration of ENV 105 enables lower radiation dosing to improve quality of life.

KROS 101 and KROS 102

Checkpoint inhibitors are immunotherapeutic agents that block proteins that suppress a potent immune response of the body against cancers and other “foreign” agents. KROS 101 and 102 are checkpoint inhibitors and agonists that enable T cells to expand and contract respectively. The global immune checkpoint inhibitor market size was $47.4 billion in 2023 and anticipated to be $189.1 billion in 2032 with a CAGR of 16,7% from 2024 to 2032 (Global Markets Insights; https://www.gminsights.com/industry-analysis/immune-checkpoint-inhibitors-market). According to the same report, there was a $22.9 billion immune checkpoint inhibitors market in North America as of 2023.

KROS 201

KROS 201 is an activated T cell therapy that targets glioblastoma. T cell therapy market size is expected to be around $20.8 billion by 2030 from its value of $4.9 billion in 2021 with a CAGR of 20.4% during the forecast period 2022-2030 (Vision Research Reports).

KROS 301

The global small-molecule cancer therapies market size was valued at $175.3 billion in 2021 and is expected to have a CAGR of 5.44% from 2022 to 2030 (Grand View Research). KROS 301 is a small molecule that targets the NF-kB pathway in cancer to prevent cancer growth and block checkpoint inhibitor expression of PD-L1.

KROS 401

The global peptide therapeutics market size was $117.3 billion in 2024 and is estimated to grow CAGR of 10.77% from 2025 to 2030 (Grand View Research). KROS 401 is a cyclic peptide that blocks IL-4 and IL-13 receptors on tumor associated macrophage to reverse immune suppression at the tumor site.

ENV 205

Cachexia is debilitating disease of muscle wasting not treatable by nutrition supplementation associated with the death of 50% of all cancer, 20% of AIDS, and 30% of COPD patients, according to [Argilés et al. (2023) Nature Reviews Clinical Oncology 20:250-264]. Cachexia is an underrecognized consequence of many chronic diseases. We believe ENV 205 is a molecule found to limit the process of muscle wasting through the capture and excretion of mitochondrial DNA in circulation. Cachexia is considered an orphan disease in the U.S. and Europe, increasing hospitalization costs and length of stay in several disease types. The specific cancer cachexia therapeutics market was over $2 billion in 2022 worldwide, with an estimated growth to to over $4 billion by 2032, according to Market.US. The application of ENV 205 as cachexia therapeutic is further supported by the demonstrated restoration of docetaxel therapy sensitivity in resistant prostate cancer models. Taxane-based therapy, inclusive of docetaxel, paclitaxel, and cabazataxel, is standard of care for majority of solid tumors (inclusive of breast cancer, non-small cell lung cancer, advanced stomach cancer, head and neck cancer and metastatic prostate cancer). Strong preclinical data suggest ENV 205 chemotherapy sensitization in a combination therapy setting and limit the development of cachexia as a single agent.

We will aggressively pursue ENV 105 and ENV 205 in pre-clinical and clinical trials. Future therapeutic targets will be developed based on the overriding mission to complement traditional cancer-targeted drugs with those that address the tumor microenvironment.

Our Strategy

Our goal is to unlock the power of the immune system on the two most pervasive problems in cancer treatment: (i) resistance to therapy and (ii) immune suppression by cancer. We believe this road will lead to major improvement in the quality of life of cancer patients and will transform the outcomes of patients. We seek to develop cutting-edge therapeutics for cancer patients that reverse the inhibitory effects of cancer on the immune system. To this end, our strategy involves rapidly and efficiently advancing our existing portfolio of innovative products through clinical development and leveraging our current industry-leading team. The strategy consists of the following:

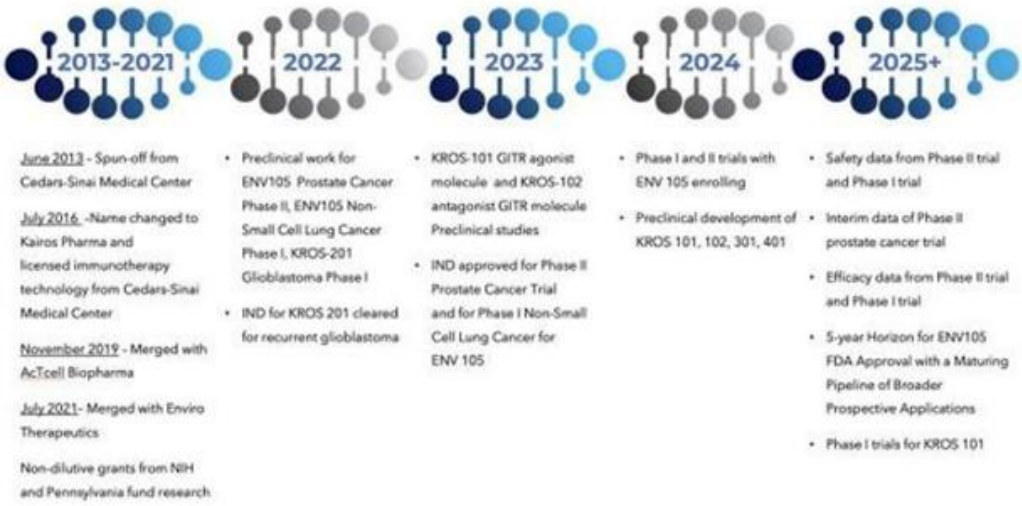
- A multi-pronged toolkit of potent and life changing therapeutics with differing modalities, targets, and stages of development. Their commonality is targeting key mechanisms of drug resistance and immune suppression by cancer.
- Leverage our academic research and clinical connections with our industry collaborations.
- Complete enrollment of prostate patients in a randomized multi-institutional Phase 2 trial of ENV 105.
- Complete enrollment in a Phase 1 trial of ENV105 for patients with non-small lung cancer on Tagrisso.
- Initiate a Phase 1 trial of activated T cell therapy for KROS 201 in patients with glioblastoma.
- Complete pre-IND studies for the checkpoint inhibitor KROS 101.
- Continue to advance our pipeline of immunotherapeutics for clinical trials.
- Maintain a portfolio of innovative therapeutics to mitigate risk.
- Leverage virtual infrastructure for efficient execution of collaborative clinical and translational research.
- Utilize internal development capabilities to leverage close academic partnerships.

In particular, we intend to deploy an aggressive, three-pronged, growth strategy that we believe will help us develop our clinical pipeline and maximize our success, consisting of strategic partnerships, commercial development, and portfolio optimization.

- ***Strategic Partnerships*** - We will focus on expanding our existing pipeline through establishing strategic partnerships with companies that have interesting products and technologies. We intend to focus on novel, early-stage and preclinical assets in a variety of therapeutic areas.

- ***Commercial Development*** - We expect to participate and assist in the commercial development activities of its assets with our strategic partners. Commercial development activities may include, but are not limited to, clinical development, market research, healthcare economics, market access, sales/marketing, and commercial launch strategies.

- ***Portfolio Optimization*** - We will continue to evaluate, prioritize, optimize, and make appropriate changes in our pipeline portfolio as market development dynamics and/or product opportunities change.



Our Team

Our Company is led by our CEO and Chairman, Dr. John S. Yu, our Chief Scientific Officer, Dr. Neil Bhowmick, our Vice President of Research and Development, Dr. Ramachandran Murali, and our Chief Financial Officer, Mr. Doug Samuelson.

Dr. Yu is a Professor and Clinical Chief in the Department of Neurosurgery and Director of the Brain Tumor Center at Cedars-Sinai Medical Center in Los Angeles, California. Dr. Bhowmick is a Professor of the Department of Medicine and Director of the Cancer Biology Program at Cedars-Sinai Medical Center. Dr. Murali is a structural biologist at Cedars-Sinai Medical Center, and the inventor, with others, of three of the patented technologies licensed to Kairos.

Intellectual Property

Overview

Dr. Yu, Dr. Bhowmick and Dr. Murali have developed certain proprietary technology, and identified other proprietary technology developed by researchers and Cedars, that the Company will pursue for commercialization. Proprietary technology invented and developed by doctors and scientists and Cedars are owned by Cedars, and then optioned and/or licensed to such doctors and scientists, or other third parties, for commercialization in partnership with Cedars. Kairos and its subsidiary Enviro have multiple such options and/or license agreements with Cedars regarding proprietary technology that the Company is pursuing for commercialization, as described below.

All of our patent rights are subject to the license agreements between the patent owner and the Company, described below.

Kairos Intellectual Property Agreements with Cedars-Sinai Medical Center

Kairos has entered into four Exclusive License Agreements with Cedars-Sinai Medical Center, which are sometimes referred to as the Kairos-Cedars license agreements, which grant Kairos exclusive licensing rights (including the right to sublicense) with respect to certain patent rights owned by Cedars to the following:

1. Method of generating activated T cells for cancer therapy, invented by Dr. John S. Yu and others.

2. Methods of use of compounds that bind to RelA of NFkB, invented by Dr. Ramanchandran Murali and others.

3. Composition and methods for treating fibrosis, invented by Dr. Ramanchandran Murali and others.

4. Compositions and methods for treating cancer and autoimmune diseases, invented by Dr. Ramanchandran Murali and others.

For the exclusive license agreement in item 1 above, Kairos is required to pay (i) an initial license fee in the mid five-figures upon the raising of $500,000 in capital, (ii) an annual maintenance fee in the low five-figures, (iii) royalties based on low single-digit percentage of patent product sales and less than one percent of other sales and (iv) other non-royalty sublicense fees ranging from a mid-single-digit to low double-digit percentage of such revenues shall be due and payable to Cedars, depending on the stage of FDA authorization at the time the sublicense revenue is generated. Non-royalty sublicense revenue would be between 5% and 35% depending on the phase of FDA testing of the product during which the sublicense agreement is signed.

In addition, Kairos is required to make payments to Cedars based on the following milestones: (i) successful completion of Phase 1 clinical trial; (ii) the successful completion of Phase 2 clinical trial and receipt of U.S. Food and Drug Administration, or FDA, or equivalent regulatory agency in another jurisdiction approval for a Phase 3 clinical trial; (iii) receipt of FDA approval; and (iv) cumulative net sales exceeding $50,000,000. If all of these milestones are met, the required milestone payments will total $4,400,000.

For each of the exclusive license agreement in items 2, 3 and 4 above, Kairos is required to (i) pay an initial license fee of $15,000, (ii) reimburse Cedars for patent protection costs ranging from the high four-figures to the mid-five-figures, (iii) pay an annual maintenance fee in the low five-figures and (iv) pay royalties based on a low single-digit percentage of net sales. The royalty obligations as to each product will terminate on a country-by-country basis concurrently with the expiration of the last to expire of a valid claim within the patent rights that covers such product, including any term extensions thereof. There are no non-royalty expiration dates. Patent expiration dates and specific jurisdictions of foreign patents that we in-license from Cedars-Sinai are listed in the Patent Table at page 100 below.

Enviro Intellectual Property Agreements with Cedars-Sinai Medical Center

On March 16, 2020, Enviro entered into two Exclusive Option Agreements with Cedars-Sinai Medical Center that gives Enviro options to enter into an Exclusive Agreement with Cedars which would grant Enviro exclusive licensing rights (including the right to sublicense) to certain patent rights owned by Cedars with respect to (1) compositions and methods for treating diseases and conditions by depletion of mitochondrial DNA from circulation for detection of mitochondrial DNA, and (2) sensitization of tumors to therapies through endoglin antagonism.

In consideration of these agreements, Enviro agreed to pay option fees of $2,000 and $3,000, respectively. Enviro's options expire nine months from the effective date. On January 9, 2021 and January 11, 2021, the parties agreed to extend both nine-month option periods for an additional six months. In consideration of these extensions, Enviro agreed to pay an extension fee of $500, and $1,000, respectively. Enviro entered into two Exclusive License Agreements with Cedars-Sinai Medical Center on June 2, 2021. Enviro and Cedars entered into:

(1) an Exclusive License Agreement for Enviro to develop, manufacture, use and sell products utilized or derived from patent rights worldwide, which include one patent application in the United States related to the "Compositions and Methods for Treating Diseases and Conditions by Depletion of Mitochondrial DNA from Circulation and for Detection of Mitochondrial DNA" invented by Dr. Neil Bhowmick and others; and

(2) an Exclusive License Agreement for Enviro to develop, manufacture, use and sell products utilized or derived from the patent rights and technical information worldwide, which include six patent applications in the United States, Australia, Canada, China, Europe and Japan related to the "Sensitization of Tumors to Therapies Through Endoglin Antagonism" invented by Dr. Neil Bhowmick and others.

The milestones agreed to were as follows:

1. Completion of preclinical studies within two years of the effective date, as stipulated in the agreement thereof (the "Effective Date");
2. Completion of toxicology studies within two and a half years of the Effective Date;
3. Obtaining IND within three years of the Effective Date; and
4. Beginning the Phase 1 trial within four years of the Effective Date.

As of the date of this Annual Report, we have completed milestones 1, 2 and 3.

Pursuant to the two Enviro-Cedars license agreements, Enviro must meet certain milestones relating commercialization, and, if not met or extended, Cedars may convert the exclusive licenses into non-exclusive licenses or to co-exclusive licenses, or terminate the licenses. In exchange for each of the licenses, Enviro is obligated to pay an upfront license fee, plus an additional fee when Enviro has raised at least $250,000 in capital company-wide for any program or purpose; provided, however, that the Company will only have to pay such fee once between both Enviro-Cedars license agreements. Enviro was also obligated to reimburse Cedars for the costs incurred for the prosecution of the patent rights subject to the Enviro-Cedars license agreements prior to the date of execution of such agreements. The aggregate potential fees that Enviro may have to pay in exchange for the licenses is approximately $690,000 as of December 31, 2024. Together, Kairos and Enviro owed a total of approximately $950,000 to Cedars, of which $750,000 was converted into 312,500 shares of common stock, or 60% of the IPO price, upon closing of the IPO. And on November 13, 2024, an additional $200,000 was converted into 150,830 shares of common stock, using a conversion price equal to 60% of the closing price on November 13, 2024. Cedars will also be entitled to receive royalty payments of a mid-single-digit percentage of net sales of products associated with the licensed patent right and less than one percent of net sales of other products derived from Cedars' technical information, with a minimum royalty year in the low five-digits due beginning on the third anniversary of the effective date of the license. To the extent Enviro derives non-royalty sublicensing revenues, a high single-digit to low double-digit percentage of such revenues shall be due and payable to Cedars, depending on the stage of FDA authorization at the time the sublicense revenue is generated. Non-royalty sublicense revenue would be between 5% and 35% depending on the phase of FDA testing of the product during which the sublicense agreement is signed.

Enviro shall pay Cedars in connection with achieving certain milestones relating to products derived from the patent rights: (i) successful completion of Phase 1 clinical trial; (ii) successful completion of Phase 2 clinical trial, receipt of FDA approval, and approval for a Phase 3 clinical trial; (iii) FDA approval of a new drug application or biologics license applications; and (iv) cumulative net sales exceeding $100,000,000. The maximum aggregate milestone payment for ENV 105 will be $7,150,000 when cumulative net sales have exceeded $100,000,000. The last-to-expire of licensed patents is scheduled to expire on June 14, 2037. Patent expiration dates, specific jurisdictions of foreign patents are listed in the Patent Table above.

The Enviro-Cedars license agreements will, unless sooner terminated, continue in effect on a country-by-country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Enviro-Cedars license agreements, unless waived by Cedars, the agreement shall automatically terminate: (a) if Enviro ceases, dissolves or winds up its business operations; (b) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of Cedars or the agreement is deemed illegal by a governmental body; (c) within 30 days for non-payment of royalties or if of Enviro fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (d) within 60 days of Enviro's failure to cure any breach or default of a material obligation under the agreements (e) within 90 days of Enviro's failure to cure any breach or default of a material obligation under the agreements; or (f) upon mutual written agreement of the parties.

Effective April 17, 2025, Enviro, Kairos and Cedars entered into a novation agreement pursuant to which the exclusive license was transferred from Enviro to Kairos, after which time Kairos accepted and assumed all obligations and liabilities under the exclusive license agreements and Enviro was relived of any further liabilities or obligations under the license agreements.

License and Supply Agreement with Tracon Pharmaceuticals, Inc.

On May 21, 2021, Enviro, the Company's formerly wholly-owned subsidiary, entered into an Enviro-Tracon license agreement with Tracon. Pursuant to the Enviro-Tracon license agreement, Tracon grants to Enviro access to inactive IND filings for "TRC105" in the United States, ownership of "TRC105" stored vials of drug product manufactured to GMP standards stored at Fisher Clinical or their designee, and assignment of Tracon's patent rights to its "CD105 technologies."

Pursuant to the Enviro-Tracon license agreement, Enviro paid Tracon an upfront fee of $100,000, and was obligated to pay Tracon an additional $500,000 upon its or its successor's completion of one or more financings through the sale of equity (or debt convertible to equity) in an amount of $10,000,000, and an additional $500,000 within 10 days of its or its successor's completion of one or more financings through the sale of equity (or debt convertible to equity) in an amount of $22,000,000. In addition, Enviro was obligated to pay Tracon a royalty of 3% of net sales on a country-by-country basis of the products subject to the agreement, and non-royalty payments of 3% of consideration for sublicensing fees. The royalty payments would terminate upon the completion of use of the TRC105 product. The non-royalty payments would terminate upon payment of $500,000 after the financing of an aggregate amount of $22,000,000 to the Company.

Prior to becoming a wholly-owned subsidiary of the Company, Enviro issued Tracon equity ownership in Enviro equal to a number of shares of restricted common stock of Enviro equal to 7% on a fully diluted and converted basis of all common and preferred shares of Enviro. Thereafter, in connection with the Enviro-Kairos share exchange, the parties agreed that Tracon would receive, in exchange for its Enviro common stock, 280,000 shares of the restricted common stock of Kairos (which was then equal to 1.41229% of the issued and outstanding shares of Kairos on a fully diluted and converted basis). Under the Enviro-Tracon license agreement, until such time as Tracon has received all of the cash consideration (as described above), Enviro or its successor in interest, shall issue to Tracon, without further consideration, any additional common stock of Enviro, or such successor in interest, necessary so that Tracon maintains ownership of shares of Enviro, or such successor in interest, equal to the Tracon-Enviro Equity on a fully diluted and converted basis of all stock in Enviro (or its successor). However, as of the date of this Annual Report, all Tracon shares in Kairos have been sold and Tracon no longer has an ownership interest in Kairos.

Pursuant to the Enviro-Tracon license agreement, which was assumed by Kairos effective April 17, 2025 pursuant to a novation agreement, we have exclusive licensing rights (which include the right to sublicense) to eight issued U.S. patents, four U.S. Utility or provisional patent applications, 24 issued patents and 24 patent applications in foreign jurisdictions. Patent expiration dates, specific jurisdictions of foreign patents are listed in the Patent Table below.

PATENT TABLE

Case Number.Sub Case	Name of the Patent	Patent No./Application No.	Status (Patent granted or Patent application)	Products or Technologies to which the Patents or Patent Applications Relate	Type of Patent Protection	Expiration Date	Jurisdiction
017431.501AU0	SENSITIZATION OF TUMORS TO THERAPIES THROUGH ENDOGLIN ANTAGONISM	2017286561	APPLICATION	ENV 105	Both a Product and a Method of Treatment Patent	2037-06-14	Australia
017313.004CA0	COMPOSITIONS AND METHODS FOR TREATING CANCER AND AUTOIMMUNE DISEASES	3,108,796	APPLICATION	KROS 101 and KROS 102	Both a Product and a Method of Treatment Patent	2039-08-08	Canada
017313.005CA0	METHOD OF GENERATING ACTIVATED T CELLS FOR CANCER THERAPY	3,150,273	APPLICATION	KROS 201	Both a Product and a Method of Treatment Patent	2040-08-10	Canada
017431.501CA0	SENSITIZATION OF TUMORS TO THERAPIES THROUGH ENDOGLIN ANTAGONISM	3026066	APPLICATION	ENV 105	Both a Product and a Method of Treatment Patent	2037-06-14	Canada
017431.502CA0	COMPOSITIONS AND METHODS FOR TREATING DISEASES AND CONDITIONS BY DEPLETION OF MITOCHONDRIAL OR GENOMIC DNA FROM CIRCULATION	3162518	APPLICATION	ENV 205	Both a Product and a Method of Treatment Patent	2040-11-25	Canada

Case Number.Sub Case	Name of the Patent	Patent No./Application No.	Status (Patent granted or Patent application)	Products or Technologies to which the Patents or Patent Applications Relate	Type of Patent Protection	Expiration Date	Jurisdiction
017313.004CN1	COMPOSITIONS AND METHODS FOR TREATING CANCER AND AUTOIMMUNE DISEASES	2024104360758.0	APPLICATION	KROS 101 and KROS 102	Both a Product and a Method of Treatment Patent	2039-08-08	China
017431.501CN0	SENSITIZATION OF TUMORS TO THERAPIES THROUGH ENDOGLIN ANTAGONISM	201780050000.4	APPLICATION	ENV 105	Both a Product and a Method of Treatment Patent	2037-06-14	China
35882-714.7111	ANTIBODY FORMULATIONS AND USES THEREOF	201810659773.9	APPLICATION	ENV 105	Both a Product and a Method of Treatment Patent	2033-09-05	China (People's Republic)
017313.004EP0	COMPOSITIONS AND METHODS FOR TREATING CANCER AND AUTOIMMUNE DESEASES	19848154.1	APPLICATION	KROS 101 and KROS 102	Both a Product and a Method of Treatment Patent	2039-08-08	European Patent
017313.005EP0	METHOD OF GENERATING ACTIVATED T CELLS FOR CANCER THERAPY	20850517.2	APPLICATION	KROS 201	Both a Product and a Method of Treatment Patent	2040-08-10	European Patent
017431.501EP0	SENSITIZATION OF TUMORS TO THERAPIES THROUGH ENDOGLIN ANTAGONISM	17814046.3	APPLICATION	ENV 105	Both a Product and a Method of Treatment Patent	2037-06-14	European Patent
017431.502EP0	COMPOSITIONS AND METHODS FOR TREATING DISEASES AND CONDITIONS BY DEPLETION OF MITOCHONDRIAL OR GENOMIC DNA FROM CIRCULATION	20893032.1	APPLICATION	ENV 205	Both a Product and a Method of Treatment Patent	2040-11-25	European Patent

Case Number.Sub Case	Name of the Patent	Patent No./Application No.	Status (Patent granted or Patent application)	Products or Technologies to which the Patents or Patent Applications Relate	Type of Patent Protection	Expiration Date	Jurisdiction
017313.002EP0	METHODS AND USE OF COMPOUNDS THAT BIND TO RELA OF NF-KB	3303286	GRANTED	KROS 301	Both a Product and a Method of Treatment Patent	2036-06-01	France, Germany, Switzerland & Liechtenstein, United Kingdom.
017313.003EP0	COMPOSITIONS AND METHODS FOR TREATING FIBROSIS	3194446	GRANTED	KROS 401	Both a Product and a Method of Treatment Patent	2035-09-18	France, Germany, Switzerland & Liechtenstein, United Kingdom.
35882-714.741	ANTIBODY FORMULATIONS AND USES THEREOF	1538/DELNP/2015	GRANTED	ENV 105	Both a Product and a Method of Treatment Patent	2033-09-05	India
35882-714.7611	ANTIBODY FORMULATIONS AND USES THEREOF	6445671	GRANTED	ENV 105	Both a Product and a Method of Treatment Patent	2033-09-05	Japan
35882-714.7612	ANTIBODY FORMULATIONS AND USES THEREOF	6602446	GRANTED	ENV 105	Both a Product and a Method of Treatment Patent	2033-09-05	Japan
017313.003JP0	COMPOSITIONS AND METHODS FOR TREATING FIBROSIS	7095990	GRANTED	KROS 401	Both a Product and a Method of Treatment Patent	2035-09-18	Japan
017313.003JP1	COMPOSITIONS AND METHODS FOR TREATING FIBROSIS	2020-148662	APPLICATION	KROS 401	Both a Product and a Method of Treatment Patent	2035-09-18	Japan
017313.004JP0	COMPOSITIONS AND METHODS FOR TREATING CANCER AND AUTOIMMUNE	7530346	GRANTED	KROS 101 and KROS 102	Both a Product and a Method of Treatment Patent	2039-08-08	Japan
017313.004JP1	COMPOSITIONS AND METHODS FOR TREATING CANCER AND AUTOIMMUNE	2024-120839	APPLICATION	KROS 101 and KROS 102	Both a Product and a Method of Treatment Patent	2039-08-08	Japan
017431.501JP0	SENSITIZATION OF TUMORS TO THERAPIES THROUGH ENDOGLIN ANTAGONISM	7092684	GRANTED	ENV 105	Both a Product and a Method of Treatment Patent	2037-06-14	Japan

Case Number.Sub Case	Name of the Patent	Patent No./Application No.	Status (Patent granted or Patent application)	Products or Technologies to which the Patents or Patent Applications Relate	Type of Patent Protection	Expiration Date	Jurisdiction
017431.502JP0	COMPOSITIONS AND METHODS FOR TREATING DISEASES AND CONDITIONS BY DEPLETION OF MITOCHONDRIAL OR GENOMIC DNA FROM CIRCULATION	2022-530781	APPLICATION	ENV 205	Both a Product and a Method of Treatment Patent	2040-11-25	Japan
017313.004KR0	COMPOSITIONS AND METHODS FOR TREATING CANCER AND AUTOIMMUNE DISEASES	10-2021-7006602	GRANTED	KROS 101 and KROS 102	Both a Product and a Method of Treatment Patent	2039-08-08	Korea, Republic of (KR)
017313.004KR1	COMPOSITIONS AND METHODS FOR TREATING CANCER AND AUTOIMMUNE DISEASES	10-2025-7000546	APPLICATION	KROS 101 and KROS 102	Both a Product and a Method of Treatment Patent	2039-08-08	Korea, Republic of (KR)
35882-714.911	ANTIBODY FORMULATIONS AND USES THEREOF	MY-180157-A	GRANTED	ENV 105	Both a Product and a Method of Treatment Patent	2033-09-05	Malaysia
35882-714.781	ANTIBODY FORMULATIONS AND USES THEREOF	368996	GRANTED	ENV 105	Both a Product and a Method of Treatment Patent	2033-09-05	Mexico

Case Number.Sub Case	Name of the Patent	Patent No./Application No.	Status (Patent granted or Patent application)	Products or Technologies to which the Patents or Patent Applications Relate	Type of Patent Protection	Expiration Date	Jurisdiction
35882-714.861	ANTIBODY FORMULATIONS AND USES THEREOF	1501001224	APPLICATION	ENV 105	Both a Product and a Method of Treatment Patent	2033-09-05	Thailand
35882-706.202	ENDOGLIN ANTIBODIES	8,221,753	GRANTED	ENV 105	Product	2030-03-31	United States of America
35882-706.302	ENDOGLIN ANTIBODIES	9,150,652	GRANTED	ENV 105	Method of treatment	2029-09-30	United States of America
35882-706.401	ENDOGLIN ANTIBODIES	9,944,714	GRANTED	ENV 105	Composition of matter	2030-03-31	United States of America
35882-714.831	ANTIBODY FORMULATIONS AND USES THEREOF	10,195,281	GRANTED	ENV 105	Product and Formulation	2034-12-25	United States of America
017313.002US0	METHODS AND USE OF COMPOUNDS THAT BIND TO RELA OF NF-KB	10,881,641	GRANTED	KROS 301	Method of treatment	2037-11-30	United States of America
017313.002US1	METHODS AND USE OF COMPOUNDS THAT BIND TO RELA OF NF-KB	10,195,281	GRANTED	KROS 301	Method of treatment	2037-11-30	United States of America
017313.003US0	COMPOSITIONS AND METHODS FOR TREATING FIBROSIS	10,245,298	GRANTED	KROS 401	Pharmaceutical composition	2035-09-18	United States of America

Case Number.Sub Case	Name of the Patent	Patent No./Application No.	Status (Patent granted or Patent application)	Products or Technologies to which the Patents or Patent Applications Relate	Type of Patent Protection	Expiration Date	Jurisdiction
017313.003US1	COMPOSITIONS AND METHODS FOR TREATING FIBROSIS	11,547,738	GRANTED	KROS 401	Method of treatment	2035-09-18	United States of America
017313.003US2	COMPOSITIONS AND METHODS FOR TREATING FIBROSIS	18/093,667	APPLICATION	KROS 401	Both a Product and a Method of Treatment Patent	2035-09-18	United States of America
017313.004US0	COMPOSITIONS AND METHODS FOR TREATING CANCER AND AUTOIMMUNE DISEASES	17/266,488	APPLICATION	KROS 101 and KROS 102	Both a Product and a Method of Treatment Patent	2039-08-08	United States of America
017313.005US0	METHOD OF GENERATING ACTIVATED T CELLS FOR CANCER THERAPY	17/633,505	APPLICATION	KROS 201	Both a Product and a Method of Treatment Patent	2040-08-10	United States of America
017431.501US1	SENSITIZATION OF TUMORS TO THERAPIES THROUGH ENDOGLIN ANTAGONISM	17/685,040	APPLICATION	ENV 105	Both a Product and a Method of Treatment Patent	2037-06-14	United States of America
017431.502US0	COMPOSITIONS AND METHODS FOR TREATING DISEASES AND CONDITIONS BY DEPLETION OF MITOCHONDRIAL OR GENOMIC DNA FROM CIRCULATION	17/779,716	APPLICATION	ENV 205	Both a Product and a Method of Treatment Patent	2040-11-25	United States of America

Corporate Reorganization

Kairos Pharma, Ltd. was originally incorporated on June 17, 2013 in the state of California as NanoGB13, Inc. The Company changed its name to "Kairos Pharma, Ltd." on July 15, 2016. On May 10, 2023, we filed a certificate of conversion with the Secretary of State of the State of California, and on the same date, we also filed with the Delaware Secretary of State a certificate of conversion converting the Company from a non-Delaware corporation to a Delaware corporation pursuant to section 265 of the Delaware General Corporation Law t. In addition, on May 10, 2023, we filed a certificate of incorporation with the Secretary of State of the State of Delaware, thus completing our conversion into a Delaware corporation. In conjunction with the Company's conversion into a Delaware corporation, on May 10, 2023, the Company conducted a 1-for-2.5 Reverse Stock Split. After the Reverse Stock Split, there were 10,334,357 shares of our common stock outstanding.

On November 13, 2019, Kairos entered into an Agreement of Merger with AcTcell Biopharma, Inc., or AcTcell, whereby the Company issued 5,045,000 shares of its common stock for all the issued and outstanding shares of AcTcell common stock. AcTcell was a California corporation that was incorporated on July 22, 2019. AcTcell's only asset at the merger date was an Exclusive License Agreement dated August 30, 2019 between AcTcell and Cedars-Sinai Medical Center. AcTcell had no liabilities at the merger date.

John S. Yu, the Company's Chairman, Chief Executive Officer and shareholder, was the sole owner of AcTcell. The acquisition of AcTcell by Kairos was treated as a transaction between entities under common control resulting in the historical costs basis of AcTcell's assets and liabilities being recognized.

Enviro was incorporated on November 15, 2019, under the law of the state of California and was an early-stage company that is focused on the development of therapeutics targeting the tumor microenvironment to complement conventional and targeted therapies designed against the cancer cells. Kairos's Chairman, Chief Executive Officer and shareholder, Dr. Yu, was also a founder and shareholder of Enviro.

On June 3, 2021, Kairos and Enviro entered into a share exchange agreement whereby Kairos acquired of all of the common stock of Enviro in exchange for stock in Kairos. In the Enviro-Kairos share exchange, the Enviro shareholders exchanged 100% of the issued and outstanding shares of Enviro (on a fully diluted basis) for 6,000,000 shares of newly issued restricted common stock of Kairos, which, as of the closing of the Enviro-Kairos share exchange: (i) represented approximately twenty percent (20%) of the outstanding shares of capital stock of the Company on a fully diluted basis, including all issued and outstanding convertible promissory notes, preferred stock, SAFEs, other securities convertible into capital stock, stock options and warrants, and after giving effect to the issuance of the shares in the Enviros-Kairos share exchange, and (ii) have voting power approximately equal to twenty percent (20%) of all shares eligible to vote on matters by the shareholders of Kairos. At the closing of the Enviro-Kairos share exchange, Kairos issued each of Dr. Yu and Dr. Neil Bhowmick (the other co-founder of Enviro) 1,860,000 of Kairos' restricted common stock in exchange for their shares of Enviro. Kairos also issued Tracon Pharmaceutical, Inc., an unaffiliated third party, 280,000 shares of Kairos restricted common stock in exchange from their shares of Enviro, which Tracon had received pursuant to a license and supply agreement between Enviro and Tracon, pursuant to which Enviro had acquired certain licensing rights from Tracon.

At the closing of the Enviro-Kairos share exchange, prior to our 1-for-2.5 reverse split conducted in 2023 and including the newly issued shares in that transaction, Kairos had approximately 19,825,957 shares of common stock issued and outstanding on a fully diluted basis (including 18,825,957 outstanding shares of common stock, and 1,000,000 warrants exercisable into 1,000,000 shares of common stock).

Effective April 17, 2025, the Company entered into novation agreements with Enviro and Enviro's licensors, Tracon and Cedars-Sinai Medical Center, pursuant to which the Company assumed all responsibilities, liabilities and obligations of Enviro under such agreements and Enviro was released from all liability. At the same time, Enviro was dissolved.

Manufacturing

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. When we begin manufacturing, we intend to use vendors that are compliant with current cGMP, in pharmaceutical production. We expect that commercial quantities of any compound and materials for our product candidates, if approved, will be manufactured in facilities and by processes that comply with FDA and other regulations.

Employees and Human Capital Resources

As of December 31, 2025, we had one full-time employee, our Chief Financial Officer, and three part-time employees (including our executive officers), each of whom is a part-time employee primarily engaged in research and development activities, and all hold M.D. or Ph.D. degrees. Aside from our Chief Financial Officer, all officers and directors of the Company worked approximately 20 hours per week in performance of their duties related to the Company. We consider our relationship with our employees to be good. None of our employees is subject to a collective bargaining agreement.

We recognize that our continued ability to attract, retain and motivate exceptional employees is vital to ensuring our long-term competitive advantage. Our employees are critical to our long-term success and are essential to helping us meet our goals. Among other things, we support and incentivize our employees in the following ways:

- ***Talent development, compensation, and retention:*** We strive to provide our employees with a rewarding work environment, including the opportunity for growth, success, and professional development. We provide a competitive compensation and benefits package, including bonus and equity incentive plans, a 401(k) plan- all designed to attract and retain a skilled and diverse workforce.

- ***Health and safety:*** We support the health and safety of our employees by providing comprehensive insurance benefits, an employee assistance program, company-paid holidays, a personal time-off program, and other additional benefits which are intended to assist employees to manage their well-being.

- ***Inclusion and diversity:*** We are committed to efforts to increase diversity and foster an inclusive work environment that supports our workforce.

Recent Financings

Initial Public Offering

On September 17, 2024, we closed on our initial public offering ("IPO") of 1,550,000 shares of common stock at $4.00 per share, for gross proceeds of $6,200,000, following our listing on the NYSE American LLC, or NYSE American. Our IPO was underwritten by Boustead Securities, LLC, acting as lead underwriter, with the underwriters receiving 7% cash compensation and warrants to purchase a total of 108,500 shares of common stock, exercisable at $4.80 per share.

Equity Line of Credit Agreement

On November 12, 2024, the Company and Helena Global Investment Opportunities I Ltd ("Helena") entered into an equity line of credit agreement (the "ELOC Agreement"), pursuant to which Helena agreed to purchase from the Company up to $30,000 shares of common stock (the "ELOC Shares"). The Company issued 670,641 shares of restricted common stock (the "Commitment Fee Shares"), valued at $900,000 (the "Issuance Value") on the date of issuance, to Helena as the "Commitment Fee" for entry into the ELOC Agreement. The ELOC Agreement will be available for the Company's use at such time following the filing, and subsequent effectiveness, of a resale registration statement registering the ELOC Shares for resale. Upon the effectiveness of the resale registration statement (the "Effective Date"), the Commitment Fee shares will be subject to a "true-up" pursuant to which, in the event the shares are valued at less than Issuance Value on the Effective Date, additional shares will be issued to Helena to bring ensure the ELOC Shares equal the Issuance Value on the Effective Date.

The ELOC Agreement will terminate upon the following events: (i) the first day of the month next following the 36-month anniversary of the date of the ELOC Agreement or (ii) the date on which Helena has purchased the full $30,000,000 of ELOC Shares.

The ELOC Agreement may be terminated by the Company after its commencement, at the Company's discretion, provided that there are no advance notices outstanding for which common stock has yet to be issued, and the Company has paid all amounts owed to Helena under the ELOC Agreement, including the Commitment Fee Shares.

January 2025 PIPE Offering

On January 14, 2025, the Company entered into a securities purchase agreement (the "Purchase Agreement") and registration rights agreement (the "Registration Rights Agreement") with the investor name therein (the "Investor") for the sale and issuance of 2,500,000 units (the "Pre-Funded Units"), with each Pre-Funded Unit consisting of a Pre-Funded Warrant to purchase one share of common stock, exercisable for $0.001 per share, and a Common Warrant to purchase one and one half shares of common stock, exercisable at $1.40 per share (the "January 2025 PIPE Offering").

In advance of closing, on January 16, 2025, the Company and the Investor entered into an amended and restated purchase agreement (the "A&R Purchase Agreement"), which amended the terms of the Purchase Agreement to include a requirement that the Company obtain shareholder approval prior to issuing in excess of 19.99% of the Company's common stock and also amended the Common Warrants to make them immediately exercisable and reduce the exercise period from 5.5 years to five years. Other terms of the agreements remained the same.

On January 16, 2025, the Company closed the January 2025 PIPE Offering for gross proceeds of $3,497,500 (or $1.399 per Pre-Funded Unit), with an additional $2,500 payable upon the Investor's exercise of the Pre-Funded Warrants in full.

Boustead Securities, LLC ("Boustead") and D. Boral Capital LLC ("D. Boral") acted as co-placement agents for the January 2025 PIPE Offering. In conjunction therewith, on January 16, 2025, the Company entered into a Placement Agent Agreement with Boustead (the "Placement Agent Agreement"). Under the terms of the Placement Agent Agreement, at closing the Company paid the Placement Agents (i) a cash commission equal to 8% of the gross proceeds (including a 1% non-accountable expense fee) and (ii) warrants to purchase a total of 175,000 shares of common stock, exercisable at $1.40 per share, with the total cash and warrant compensation split equally between Boustead and D. Boral.

On January 20, 2025, the Company obtained the approval of 55.4% of the shareholders (the "Majority Shareholders") for the issuance in excess of 19.99% of the Company's common stock at a price below market value, in compliance with Rule 713 of the NYSE American LLC Company Guide. On February 10, 2025, the Company filed the definitive Schedule 14C and the shareholder approval became effective on March 1, 2025.

January 2026 At-the-Market Offering

On January 12, 2026, we entered into an at-the-market ("ATM") offering agreement (the "ATM Agreement") with H.C. Wainwright Co., LLC (the "Placement Agent") for the sale, from time to time, of up to $4,524,949 shares of our common stock. We registered the common stock offered under the ATM pursuant to prospectus supplement filed in conjunction with our shelf registration statement on Form S-3 (SEC File No. 333-292686), which was declared effective on January 23, 2026. Pursuant to the ATM Agreement, the Placement Agent is entitled to a placement agent fee of 3.0% of the gross sale price of shares sold under the ATM.

ITEM 1A. RISK FACTORS

Risks Related to Our Financial Position and Capital Needs

We are a small development-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

We are a small development-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. There can be no assurance that we will, or if we do, when we will, obtain approval to commercialize our products and potentially generate revenue. We have incurred significant losses since our inception and we expect to incur losses over the next several years and may never achieve or maintain profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our common stock and could impair our ability to raise capital, expand our business, maintain our research and development efforts, or continue our operations. A decline in the value of our common stock could also cause you to lose all or part of your investment.

We require substantial additional funding to meet our financial needs and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to delay, reduce, or altogether cease our current and future product development programs or future commercialization efforts.

We will need to obtain substantial additional funding in connection with our continuing operations and planned activities. Our future capital requirements will depend on many factors, including:

- the timing, progress, and results of our ongoing and future clinical trials of our current in-development products;
- the costs, timing, and outcome of regulatory review of our current in-development products and any of our future product candidates;
- the scope, progress, results, and costs of identifying, obtaining, and conducting preclinical development, laboratory testing, and clinical trials of future product candidates that we may pursue;
- the cost and timetable of manufacturing processes for development, clinical trials, and potential commercial use;
- the number and development requirements of future product candidates that we may pursue;
- the amount of funding that we receive under our non-dilutive funding opportunities, including government awards and government awards, if any, that we may apply for;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales, and distribution, for our current in-development products or any future product candidates that receive marketing approval;
- the pricing and revenue, if any, received from commercial sales of our current in-development products or any future product candidates that receive marketing approval;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining, and enforcing our intellectual property rights, and defending any intellectual property-related claims;
- the costs of operating as a public company; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive, and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our current in-development products and any of our future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for several years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or altogether cease our research and development programs or future commercialization efforts.

Raising additional capital will likely cause dilution to our stockholders, restrict our operations, or require us to relinquish rights to our current in-development products or technologies or any of our future product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends.

If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs, or our current in-development products or any future product candidates, or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our development of our current in-development products or any future product candidate or future commercialization efforts or grant rights to a third party to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

We have limited resources and limited operating history. There is only a limited basis upon which to evaluate our prospects for achieving our intended business objectives. We have not yet demonstrated the ability to successfully complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product, arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

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

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of our current in-development products or any of our future product candidates, our expenses could increase.

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 have a greater likelihood of success.

Because we have limited financial and management resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development programs 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 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 to such product candidate.

Risks Related to Development, Clinical Testing, Manufacturing and Regulatory Approval

We are heavily dependent on the success of our initial drug candidates, which are still under clinical development, and if any of these drugs does not receive regulatory approval or is not successfully commercialized, our business may be harmed.

We do not have any products that have gained regulatory approval by the FDA or comparable foreign regulatory authorities. As a result, our business is dependent on our ability to successfully complete clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize one or more drug therapies in a timely manner. We cannot commercialize our drug therapies in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize our drug therapies outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our drug therapies for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, generally including two adequate and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that a drug candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. Even if we were to successfully obtain approval of one of our drug therapies from the FDA or comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one or more of our drug therapies in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any other candidate that we may in-license, develop or acquire in the future. Furthermore, even if we obtain regulatory approval for one of our drug therapies, we will still need to develop a commercial organization, establish commercially viable pricing and obtain approval for adequate reimbursement from third-party and government payors. If we are unable to successfully commercialize one or more of our drug therapies, we may not be able to earn sufficient revenue to continue our business.

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

Our current in-development products and our future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable foreign regulatory authorities, with regulations differing from country to country. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We currently do not have any products approved for sale in any jurisdiction. We as a company only have limited experience in filing and supporting the applications necessary to gain marketing approvals and may rely on third-party contract research organizations to assist us in this process.

The time required to obtain approval, if any, 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 the substantial discretion of the regulatory authorities, government budget, and funding levels and statutory, regulatory, and policy changes. Average review times at the FDA have fluctuated in recent years, and disruptions at the FDA and other agencies may slow the time necessary for new drugs to be reviewed and/or approved. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, including the FDA, have had to furlough nonessential employees and stop routine activities. Events like this could significantly impact the ability of the FDA to timely review and process our regulatory submissions.

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. For instance, any reorganization and rededication of critical resources, at the FDA and within similar governmental health authorities across the world, may impact the ability of new products and services from being developed or commercialized in a timely manner. Regulations and requirements vary among jurisdictions, including in Europe and Japan. We have not obtained regulatory approval for any product candidate, and it is possible that none of our current in-development products or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We are not permitted to market any product candidate in the United States until we receive regulatory approval of an NDA from the FDA.

In order to obtain approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate to the satisfaction of the FDA or foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe that the nonclinical or clinical data for a product candidate is promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for product candidates either prior to or post-approval, and it may otherwise object to elements of our clinical development program.

We have not submitted a marketing application for any product candidates in any country or region. Any marketing application must include extensive preclinical, nonclinical, and clinical data and supporting information to establish the product candidate's safety and efficacy for each desired indication. The marketing application(s) must also include significant information regarding the chemistry, manufacturing, and controls for the product candidate. Obtaining marketing authorization is a lengthy, expensive, and uncertain process. The FDA, EMA, PMDA, TGA, and other comparable regulatory authorities have substantial discretion in the review and approval process and may refuse to accept for filing any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical, or other studies. Foreign regulatory authorities have differing requirements for approval of drugs with which we must comply prior to marketing. There can be no assurance that any foreign regulatory authorities will accept FDA approval as sufficient to support approval in that country. Obtaining marketing approval for marketing of a product candidate in one country does not ensure that we will be able to obtain marketing approval in other countries, but the failure to obtain marketing approval in one jurisdiction could negatively affect our ability to obtain marketing approval in other jurisdictions. The FDA or any foreign regulatory bodies can delay, limit or deny approval of our current in-development products or other future product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for many reasons, including:

- disagreement with the design or implementation of our clinical trials;

- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval (for example, otherwise positive clinical results may be called into question if patient reported outcomes introduce ambiguity due to factors such as co-morbidities and other underlying patient issues);
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that our product candidates are safe and effective for the proposed indication;
- disagreement with the interpretation of data from nonclinical studies or clinical trials;
- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- requirements for additional nonclinical studies or clinical trials;
- disagreement regarding the formulation, labeling, and/or the specifications we propose for our product candidates; or
- changes in a policies, requirements, or regulations rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage complete the FDA or foreign regulatory approval processes and are successfully commercialized. The lengthy review process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval, which would significantly harm our business, financial condition, results of operations, and prospects.

Even if we eventually receive approval of an NDA or foreign marketing application for our product candidates, the FDA, or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials, often referred to as Phase 4 clinical trials, and the FDA may require the implementation of a REMS, which may be required to ensure safe use of the drug after approval. The FDA or the applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, and the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all.

Most of our product candidates are still in the preclinical stage, and the risk of failure for such product candidates is high. In order to obtain FDA approval to market a new biologic we must demonstrate proof of safety, purity and potency, including efficacy, in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned clinical trials in humans. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our current or future product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time of such testing may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are conducting preclinical testing and studies may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including but not limited to: an inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical studies; delays in reaching a consensus with regulatory agencies on study design; any setbacks or delays on account of any pandemic; and the FDA or foreign regulatory authorities not permitting the reliance on preclinical or other data from published scientific literature.

Clinical trials are expensive, time-consuming and difficult to design and implement, and involve an uncertain outcome.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe, pure and potent in humans. Clinical testing is expensive and can take many years to complete, and its outcome is highly uncertain. Failure can occur at any time during the clinical trial process and our future clinical trial results may not be successful. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop.

Failure can occur at any time during the clinical trial process. Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, our drug therapies may not have favorable results in later preclinical and clinical studies or receive regulatory approval. We may experience delays in initiating and completing any clinical trials that we intend to conduct, and 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, or at all. Many 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 marketing approval of our product candidates. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or other regulatory authorities may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory approval to commence and/or continue to conduct a trial, including but not limited to obtaining IND approval by FDA;
- reaching an 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;
- obtaining Institutional Review Board, or IRB, approval at each site, or Independent Ethics Committee, or IEC, approval at sites outside the United States;
- recruiting suitable patients to participate in a trial in a timely manner and in sufficient numbers;
- having patients complete a trial or return for post-treatment follow-up;
- imposition of a clinical hold by regulatory authorities, or IRBs, including as a result of unforeseen safety issues or side effects or failure of trial sites to adhere to regulatory requirements or follow trial protocols;
- clinical sites deviating from trial protocol, failing to adequately enroll study subjects, committing fraud or other violations of regulatory requirements, or dropping out of a trial, which can render data from that site unusable in support of regulatory approval;
- addressing patient safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites; or
- manufacturing sufficient quantities of our drug therapies for use in clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs or IECs of the institutions in which such trials are being conducted, the Data Safety Monitoring Board, or DSMB, for such trial or the FDA or other 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 other 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 drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance, as described in "Item 1A Risk Factors- Risks Related to Our Dependence on Third Parties."

Treatment of cancer patients with our oncology product candidates may be used in combination with other cancer drugs, such as other immuno-oncology agents, monoclonal antibodies or other protein-based drugs or small molecule anti-cancer agent such as targeted agents or chemotherapy, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. Additionally, our product candidates could potentially cause adverse events. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. As described above, any of these events could prevent us from obtaining regulatory approval or achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products. Because all of our product candidates are derived from our platform technologies, a clinical failure of one of our product candidates may also increase the actual or perceived likelihood that our other product candidates will experience similar failures.

Of the large number of products in development, only a small percentage successfully complete the FDA or comparable foreign regulatory authorities' approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical testing and receive approval of a marketing application for our product candidates, the FDA or the comparable foreign regulatory authorities may grant approval contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authorities also may approve a product candidate for a more limited indication or patient population than we originally request, and the FDA or comparable foreign regulatory authorities may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects.

In addition, the FDA or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

If we experience delays in the completion, or termination, of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down the development and approval process for our product candidates and jeopardize our ability to commence product sales and generate revenues. 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.

Future legislation, and/or regulations and policies adopted by the FDA, the EMA, or comparable regulatory authorities, may increase the time and cost required for us to conduct and complete clinical trials of our current in-development products or other future product candidates.

The FDA has established regulations to govern the drug development and approval process, as have foreign regulatory authorities. The policies of the FDA and other regulatory authorities may change and additional laws may be enacted or government regulations may be promulgated that could prevent, limit, delay, or alternatively accelerate regulatory review of our current in-development products or other future product candidates. Further, disruptions at the FDA and other agencies may prolong the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several 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. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our product candidates are based on novel technologies, which make it difficult to predict the timing, results and cost of product candidate development and likelihood of obtaining regulatory approval.

We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter and use of our platform technologies may not ever result in marketable products. We may also experience delays in developing a sustainable, reproducible, and scalable manufacturing process or transferring that process to commercial partners or establishing our own commercial manufacturing capabilities, which may prevent us from completing our clinical trials or commercializing any products on a timely or profitable basis, if at all.

Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.

As we develop our drug therapies and initiate clinical trials of our additional drug therapies, serious adverse events, or SAEs, undesirable side effects, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective or in which efficacy is more pronounced or durable. Should we observe SAEs in our clinical trials or identify other undesirable side effects or other unexpected findings depending on their severity, our trials could be delayed or even stopped, and our development programs may be halted entirely.

Even if our product candidates initially show promise in early clinical trials, the side effects of drug therapies are frequently only detectable after they are tested in larger, longer and more extensive clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the drug therapy or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development or after approval and are determined to be attributed to our product candidate, we may be required to develop a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Product-related side effects could also result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or ADA caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, “Dear Healthcare Provider” letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product is administered or conduct additional clinical trials;
- the product may become less competitive, and our reputation may suffer;
- we may decide to remove the product from the marketplace; and
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties.

Positive results from preclinical studies and early-stage clinical trials may not be predictive of future results. Initial positive results in any of our clinical trials may not be indicative of results obtained when the trial is completed or in later stage trials.

The results of preclinical studies may not be predictive of the results of clinical trials. Preclinical studies and early-stage clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules, and the results of any early-stage clinical trials may not be predictive of the results of later-stage, large-scale efficacy clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs and biological products proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies, and any such setbacks in our clinical development could have a material adverse effect on our business and operating results.

Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, the results of our preclinical studies may not be predictive of the results of outcomes in human clinical trials. For example, our current or future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show desired pharmacological properties or produce the necessary safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Even if we are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

As an organization, we have limited experience designing and implementing clinical trials and we have never conducted pivotal clinical trials. Failure to adequately design a trial, or incorrect assumptions about the design of the trial, could adversely affect the ability to initiate the trial, enroll patients, complete the trial, or obtain regulatory approval on the basis of the trial results, as well as lead to increased or unexpected costs and in delayed timelines.

The design and implementation of clinical trials is a complex process. We have limited experience designing and implementing clinical trials, and we may not successfully or cost-effectively design and implement clinical trials that achieve our desired clinical endpoints efficiently, or at all. A clinical trial that is not well designed may delay or even prevent initiation of the trial, can lead to increased difficulty in enrolling patients, may make it more difficult to obtain regulatory approval for the product candidate on the basis of the study results, or, even if a product candidate is approved, could make it more difficult to commercialize the product successfully or obtain reimbursement from third-party payors. Additionally, a trial that is not well-designed could be inefficient or more expensive than it otherwise would have been, or we may incorrectly estimate the costs to implement the clinical trial, which could lead to a shortfall in funding. We also expect to continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our current or future product candidates we develop and our business could be materially harmed. Consequently, we may be unable to successfully and efficiently execute and complete clinical trials that are required for biologics license application, or BLA submission and FDA approval of our current or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop.

Our business is dependent on our ability to advance our current and future product candidates through clinical trials, obtain marketing approval and ultimately commercialize them.

We are early in our development efforts. Most of our product candidates are not yet in clinical trials. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of our current product candidates and any other current or future product candidates we develop, which may never occur. Our current product candidates and any future product candidates we develop will require additional preclinical or clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other jurisdictions, demonstration of effectiveness to pricing and reimbursement authorities, sufficient manufacturing supply for both preclinical and clinical development and commercial production, building of a commercial organization and substantial investment and significant marketing efforts before we generate any revenues from product sales.

The clinical and commercial success of our current and future product candidates will depend on several factors, including the following: timely and successful completion of preclinical studies and our clinical trials; sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials; our plans to successfully submit IND applications with the FDA for our current and future product candidates; our ability to complete preclinical studies for current or future product candidates; successful enrollment in, including maintaining or reaching target enrollment levels during the COVID-19 pandemic, and completion of clinical trials; successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended patient populations; our ability to establish agreements with third-party manufacturers on a timely and cost efficient manner; whether we are required by the FDA or comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned or anticipated to support approval of our product candidates; acceptance of our proposed indications and the primary endpoint assessments evaluated in the clinical trials of our product candidates by the FDA and comparable foreign regulatory authorities; receipt and maintenance of timely marketing approvals from applicable regulatory authorities; successfully launching commercial sales of our product candidates, if approved; the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates, if approved; entry into collaborations to further the development of our product candidates; obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates; acceptance of the benefits and uses of our product candidates, if approved, by patients, the medical community and third-party payors; maintaining a continued acceptable safety, tolerability and efficacy profile of the product candidates following approval; our compliance with any post-approval requirements imposed on our products, such as post-marketing studies, a Risk Evaluation and Mitigation Strategy, or REMS, or additional requirements that might limit the promotion, advertising, distribution or sales of our products or make the products cost prohibitive; competing effectively with other therapies; obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and enforcing and defending intellectual property rights and claims. There are multiple risks associated with developing companion diagnostics to ENV 105, ENV 205, and KROS 301 and there is no guarantee that these companion diagnostics will be approved by the FDA or comparable foreign regulatory agencies.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our current or future product candidates, and could otherwise materially harm our business. Successful completion of preclinical studies and clinical trials does not mean that any of our current or future product candidates we develop will receive regulatory approval. Even if regulatory approvals are obtained, we could experience significant delays or an inability to successfully commercialize our current and any future product candidates we develop, which would materially harm our business. If we are not able to generate sufficient revenue through the sale of any current or future product candidate, we may not be able to continue our business operations or achieve profitability.

Interim, topline and preliminary data from our clinical trials may change as more patient data become available 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 preliminary, interim or topline 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 as patient enrollment and treatment continues and more patient data become available. Adverse differences between previous preliminary or interim data and future interim or final data could significantly harm our business prospects. We may also announce topline data following the completion of a preclinical study or clinical trial, which may be subject to change following a more comprehensive review of the data related to the particular study or trial. 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 fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such 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, interim, topline and preliminary data should be viewed with caution until the final data are available.

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 or product and our Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. 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 our product candidates, our business, operating results, prospects or financial condition may be harmed.

We may face future business disruption and related risks resulting from pandemic, epidemic or outbreak of an infectious disease, any of which could have a material adverse effect on our business.

The development of our drug candidates could be disrupted and materially adversely affected in the future by a pandemic, epidemic or outbreak of an infectious disease like the outbreak of COVID-19. The spread of an infectious disease may result in the inability of our suppliers to deliver components or raw materials on a timely basis or materially and adversely affect our collaborators and out-license partners' ability to perform preclinical studies and clinical trials. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business and manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. The extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Disruptions at the FDA and other government agencies 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 products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency 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. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

If a prolonged government shutdown occurs, or if global health concerns continue to 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.

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.

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our discovery and development on select product candidates and indications. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued using our platform technologies. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. 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 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 also 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 to such product candidate.

We may not be successful in our efforts to identify or discover additional product candidates in the future.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our inability to design such product candidates with the properties that we desire; or
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable additional candidates for preclinical and clinical development, our opportunities to successfully develop and commercialize therapeutic products will be limited.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our drug therapy candidates, our business will be substantially harmed.

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 the 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 candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that we will never obtain regulatory approval for any of our drug therapy candidates. We are not permitted to market any of our product candidates in the United States until we receive regulatory approval of a NDA from the FDA. Our ability to obtain approval by the FDA or other regulatory authorities can be adversely impacted for various reasons including:

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a candidate is safe and effective for its proposed indication;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our candidates, or other products containing the active ingredient in our candidates;
- negative or ambiguous results from our clinical trials or results that 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 a 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 development candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and we may be required to conduct additional clinical trials;
- the FDA or comparable foreign authorities may disagree regarding the formulation, labeling and/or the specifications of our candidates;
- the FDA or comparable foreign regulatory authorities may fail to approve or find deficiencies with the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

- the FDA or comparable foreign regulatory authorities may inspect and find deficiencies at the clinical trial sites we use to conduct our clinical studies; 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.

Prior to obtaining approval to commercialize a candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or foreign regulatory agencies, that such candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. A single-study approach is permissible in certain circumstances, particularly in oncology, but such circumstances are exceptional and FDA may not agree with that proposed approach, and thus we may be required to conduct two phase 3 trials.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our candidates or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the adequacy of the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities may disagree with our safety interpretation of our drug;
- the FDA or comparable foreign regulatory authorities may disagree with our efficacy interpretation of our drug; or
- the FDA or comparable foreign regulatory authorities may regard our CMC package as inadequate, and more particularly:
- if our NDA does not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;
- if the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;
- if the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity;
- if the FDA determines that it has insufficient information to determine whether such drug is safe for use under such conditions;
- if based on information we submit and any other information before the FDA, the FDA determines there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or
- if the FDA determines that our labeling is false or misleading in any particular way.

Of the large number of drugs that enter clinical development, only a small percentage successfully complete the regulatory approval processes and are approved and commercialized. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market of any of our drug therapy candidates, which would significantly harm our business, results of operations and prospects.

In addition, the FDA or an applicable foreign regulatory agency also may approve a product candidate for a more limited indication or patient population than we originally requested, the FDA or foreign regulatory agency 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, or may require warnings, other safety-related labeling information, or impose post-market safety requirements, including distribution restrictions, that negatively impact the commercial potential of the drug. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Patient enrollment and retention in clinical trials depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the nature of the trial protocol;
- the existing body of safety and efficacy data with respect to the product candidate;
- the proximity of patients to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating;
- competing clinical trials being conducted by other companies or institutions;
- our ability to maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- delays or difficulties in enrollment and completion of studies due to any pandemic, epidemic or outbreak of an infectious disease.

Results of preclinical studies, early clinical trials or analyses may not be indicative of results obtained in later trials.

The results of preclinical studies, early clinical trials or analyses of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In addition, conclusions based on promising data from analyses of clinical results may be shown to be incorrect when implemented in prospective clinical trials. Even if our clinical trials for our drug therapy candidates are completed as planned, we cannot be certain that their results will support the safety and efficacy sufficient to obtain regulatory approval.

Serious adverse events or undesirable side effects caused by any of our drug therapy candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of any clinical trial we conduct could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If unacceptable side effects arise in the development of our candidates, we, the FDA or the IRBs at the institutions in which our studies are conducted, or the DSMB, if constituted for our clinical trials, could recommend a suspension or termination of our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of a product candidate for any or all targeted indications. In addition, drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete a trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our development candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of a product candidate, if approved, and could significantly harm our business, results of operations and prospects.

The market opportunities for any current or future product candidate we develop, if approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Cancer therapies are sometimes characterized as first-line, second-line or third-line, and the FDA often approves new therapies initially only for third-line use. Second- and third-line therapies are administered to patients when prior therapy is not effective. The number of patients who receive second- and third-line treatment is significantly smaller than the number of patients who receive first-line treatment. We may initially seek approval for our product candidates we develop as second- or third-line therapies. If we do so, for those products that prove to be sufficiently beneficial, if any, we would expect potentially to seek approval as a first-line therapy, but there is no guarantee that any product candidate we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the types of cancer or autoimmune diseases we are targeting may turn out to be lower than expected. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

We have never obtained marketing approval for a drug therapy candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our development candidates.

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our development candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our development candidates. If the FDA does not accept or approve our NDAs for our development candidates, it may require that we conduct additional clinical, preclinical or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our development candidates, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

Even if we obtain FDA approval for any of our drug therapy candidates in the United States, we may never obtain approval for or commercialize them in any other jurisdiction, which would limit our ability to realize their full global market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. 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.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we obtain regulatory approval for any development candidate, we will still face extensive and ongoing regulatory requirements and obligations and any development candidates, if approved, may face future development and regulatory difficulties.

The FDA and other federal and state agencies, including the U.S. Department of Justice, or the DOJ, closely regulate compliance with all requirements governing prescription drug products, including requirements pertaining to marketing and promotion of drugs in accordance with the provisions of the approved labeling and manufacturing of products in accordance with cGMP requirements. The FDA and DOJ impose stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our current in-development products or our future product candidates for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of such requirements may lead to investigations alleging violations of the Food, Drug and Cosmetic Act and other statutes, including the False Claims Act and other federal and state health care fraud and abuse laws as well as state consumer protection laws.

Any candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising and promotional activities for such product, among other things, will be subject to extensive and ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and drug listing requirements, continued compliance with current Good Manufacturing Practice, or cGMP, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping and Good Clinical Practice, or GCP, requirements for any clinical trials that we conduct post-approval.

Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval, including a requirement to implement a REMS. If any of our product candidates receive marketing approval, the accompanying label may limit the approved indicated use of the product candidate, which could limit sales of the product candidate. The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use, and if we market our products for uses beyond their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act, or FDCA, relating to the promotion of prescription drugs may lead to FDA enforcement actions and investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

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

- litigation involving patients taking our product candidates;
- restrictions on such products, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of products;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our product candidates;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Further, the FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. 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 marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability. We also 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.

Even if we obtain marketing approvals for our current in-development products or any future product candidates, the terms of approvals and ongoing regulation of such product candidates may limit how we manufacture and market the product candidates and compliance with such requirements may involve substantial resources, which could materially impair our ability to generate revenue.

Even if marketing approval of any of our current in-development products or any future product candidates is granted, an approved product and its manufacturer and marketer are subject to ongoing review and extensive regulation, including the potential requirements to implement a risk evaluation and mitigation strategy or to conduct costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements including ensuring that quality control and manufacturing procedures conform to cGMP, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We and our contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMP.

Accordingly, assuming we receive marketing approval for one or more product candidates, we and our contract manufacturers will continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance, and quality control. If we are not able to comply with post-approval regulatory requirements, we could have the marketing approvals for our product candidates withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Non-compliance by us or any future collaborator with regulatory requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, also can result in significant financial penalties. Similarly, failure to comply with the EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

We may seek a Breakthrough Therapy designation for one of our drug therapy candidates from the FDA. However, we might not seek such designation or be granted the designation by the FDA if sought, and even if we are granted the designation, it may not lead to a faster development or regulatory review or approval process.

We may seek a Breakthrough Therapy designation for one or more of our drug therapy candidates. Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). For purposes of Breakthrough Therapy designation, clinically significant endpoint generally refers to an endpoint that measures an effect on irreversible morbidity or mortality (IMM) or on symptoms that represent serious consequences of the disease. A clinically significant endpoint can also refer to findings that suggest an effect on IMM or serious symptoms. For drugs 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. Drugs designated as breakthrough therapies by the FDA may also be eligible for fast-track designation (under a separate request), priority review, or accelerated approval, if supported by clinical data at the time the NDA is submitted to the FDA. FDA encourages a Breakthrough Therapy designation request to be submitted, and received by FDA, no later than the end-of-phase-2 meetings. Even if granted, accelerated approval status does not guarantee an accelerated review or marketing approval by the FDA.

Designation as a Breakthrough Therapy is within the discretion of the FDA both at the time of the submission of such a request, and during FDA's review of the drug and supporting data. Even if we believe that one of our candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation or may grant such a designation and subsequently rescind the designation prior to approval. Even if we receive and maintain Breakthrough Therapy designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Risks Related to the Commercialization of Our Current In-Development Products and Our Future Product Candidates

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

Even if we obtain approvals from the FDA, the EMA, the PMDA, the TGA, or other comparable regulatory agencies and are able to initiate commercialization of our current in-development products or any future product candidates we develop, the product candidate may not achieve market acceptance among physicians, patients, and third-party payors and, ultimately, may not be commercially successful. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

If the market size of any product candidate that obtains regulatory approval is significantly smaller than we anticipate, it may not achieve market acceptance or commercial success. This could significantly and negatively impact our business, financial condition, and results of operations.

If we are unable to establish sales, marketing, and distribution capabilities for our current in-development products or our future product candidates, or enter into sales, marketing, and distribution agreements with third parties, we may not be successful in commercializing our product candidates, if and when they are approved.

We do not have a sales or marketing infrastructure and have limited experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization or enter into collaboration, distribution, and other marketing arrangements with one or more third parties to commercialize such product candidate. In the United States, we intend to build a commercial organization to target areas with the greatest incidence of treatments for cancers and other indications to which our drugs and therapies are targeted and recruit experienced sales, marketing, and distribution professionals. The development of sales, marketing, and distribution capabilities will require substantial resources, will be time-consuming, and could delay any product launch. We may decide to work with regional specialty pharmacies, distributors, and/or multi-national pharmaceutical companies to leverage their commercialization capabilities to commercialize any product candidate for which we may obtain regulatory approval outside of the United States.

If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire a sales force in the United States that is sufficient in size or has adequate expertise to target the areas that we intend to target. If we are unable to establish a sales force and marketing and distribution capabilities, our operating results may be adversely affected.

Factors that may inhibit our efforts to commercialize our drugs on our own include:

- our inability to recruit, train, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage compared to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- unforeseen costs and limitations with regard to setting up a distribution network.

If we are unable to establish our own sales, marketing, and distribution capabilities in the United States and other jurisdictions in which our current in-development products or any future product candidates are approved and, instead, enter into arrangements with third parties to perform these services, our revenues and profitability, if any, are likely to be lower than if we were to sell, market, and distribute any product candidates that we develop ourselves. We may not be successful in entering into arrangements with third parties to sell, market, and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively. If we do not establish sales, marketing, and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates.

Coverage and adequate reimbursement may not be available for any of our in-development products or any future product candidates, which could make it difficult for us to sell profitably, if approved.

Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third-party payors, including government health administration authorities, managed care organizations and other private health insurers. Third-party payors decide which therapies they will pay for and establish reimbursement levels. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a payor's formulary generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs, and providers are unlikely to prescribe our drugs, unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our drugs and their administration.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any of our current in-development products and any future product candidates that we develop.

If we are unable to successfully develop any required companion diagnostic tests for our product candidates, experience significant delays in doing so, or rely on third parties in the development of such companion diagnostic tests, we may be unable to realize the full commercial potential of our product candidates.

We will strive to develop companion biomarkers for all drugs in our portfolio and to evaluate whether a companion diagnostic test will be required for any of our product candidates. In general, the FDA expects to review and approve simultaneously NDA and pre-market approval submissions for a therapeutic and its companion diagnostic, respectively, so any delay in diagnostic approval could delay drug approval. On April 13, 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. We will continue to evaluate the impact of this guidance on our companion diagnostic development and strategy. This guidance and future issuances from the FDA and other regulatory authorities may impact our development of a companion diagnostic for our product candidates and result in delays in regulatory approval. We may be required to conduct additional studies to support a broader claim. Also, to the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, if any, we may be forced to abandon any of our companion diagnostic development plans or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our to be approved products, if any, and our business operations.

We may rely on third parties for the design, development, and manufacture of companion diagnostic tests for our product candidates that require such tests. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. If we or such third parties are unable to successfully develop companion diagnostics, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of our product candidates may be adversely affected or we may not obtain marketing approval, and we may not realize the full commercial potential of our product candidates.

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

The use of any of our drug therapy candidates we may develop in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business
- reputation and significant negative media attention;
- withdrawal of participants from our clinical trials;
- significant costs to defend the litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- inability to commercialize THIO or any other product candidate;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- decreased market demand for any product; and
- loss of revenue.

The product liability insurance coverage carry may not be sufficient to reimburse us for any expenses or losses we may suffer. We intend to acquire insurance coverage to include larger clinical studies, different countries and the potential sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. A successful product liability claim, or series of claims, brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect the results of our operations and business, including preventing or limiting the commercialization of any product candidates we develop.

We hold $5 million in global product liability insurance coverage with a per incident limit of $5 million annually, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of any product candidates. Insurance coverage is increasingly expensive. We may not be able to obtain or maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise, if at all. Product liability insurance policies contain various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with current or future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

There are a variety of risks associated with marketing our current in-development products or any future product candidates internationally, which could affect our business.

We may seek regulatory approvals for ENV 105 and/or any of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement landscapes in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability.

Risks Related to Our Dependence on Third Parties

Our employees and independent contractors, including principal investigators, clinical trial sites, contract research organizations, or CROs, consultants, vendors, and any third parties we may engage in connection with development and commercialization, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

Our employees and independent contractors, including principal investigators, clinical trial sites, consultants, vendors and any third parties we may engage in connection with development and commercialization of our product candidates, could engage in misconduct, including intentional, reckless or negligent conduct or unauthorized activities that violate: the laws and regulations of the FDA or other similar regulatory requirements of other authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; manufacturing standards; data privacy, security, fraud and abuse and other healthcare laws and regulations; or laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creation of fraudulent data in preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, 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. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, other U.S. federal healthcare programs or healthcare programs in other jurisdictions, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

We rely on single-sourced third parties to conduct the preclinical and nonclinical studies, clinical trials, and manufacture of our clinical trial material for our current in-development products and our future product candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such studies, trials, and manufacturing services or failing to comply with applicable regulatory requirements.

We have engaged contract research organizations, or CROs, to conduct our ongoing and planned preclinical and nonclinical studies, clinical trials and manufacture of our clinical trial material. We also expect to engage CROs for any of our other future product candidates that may progress to clinical development. We expect to rely on CROs, as well as other third parties, such as clinical data management organizations, medical institutions, and clinical investigators, to conduct those preclinical and nonclinical studies, clinical trials, and manufacture of our clinical trial material. Currently, we rely on single source third-party research institutions, laboratories, clinical research and manufacturing organizations for research and development. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements or fail to enter into alternative arrangements in a timely manner, our product development activities would be delayed.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Similar regulatory requirements apply outside the United States, including the International Council for Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use, or the ICH. We are also required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so by us or third parties can result in FDA refusal to approve applications based on the clinical data, enforcement actions, adverse publicity, and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our current in-development products and our future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize such product candidates.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any New Drug Application, or NDA, we submit. Any such delay or rejection could prevent us from commercializing our current in-development products or any future product candidates.

We will rely on third-party contract manufacturing organizations, or CMOs, for the production of clinical supply of our drug therapy candidates and intend to rely on CMOs for the production of commercial supply our drug therapies, if approved. Our dependence on CMOs may impair the development and commercialization of the drug, which would adversely impact our business and financial position.

We have limited personnel with experience in manufacturing, and we do not own facilities for manufacturing. Instead, we rely on and expect to continue to rely on CMOs for the supply of cGMP grade clinical trial materials and commercial quantities of any candidates we develop, if approved. Reliance on CMOs may expose us to more risk than if we were to manufacture our product candidates ourselves. We intend to have manufactured a sufficient clinical supply of our drug therapy substances to enable us to complete our clinical trials, and we have also engaged a CMO to provide clinical and commercial supply of the drug product.

The facilities used to manufacture our product candidates must be inspected by the FDA and comparable foreign authorities. While we provide oversight of manufacturing activities, we do not and will not control the execution of manufacturing activities by, and are or will be essentially dependent on, our CMOs for compliance with cGMP requirements for the manufacture of our product candidates. As a result, we are subject to the risk that our product candidates may have manufacturing defects that we have limited ability to prevent. If a CMO cannot successfully manufacture material that conforms to our specifications and the regulatory requirements, we will not be able to secure or maintain regulatory approval for the use of our product candidates in clinical trials, or for commercial distribution of our product candidates, if approved. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or comparable foreign regulatory authority finds deficiencies with or does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval or finds deficiencies in the future, we may need to find alternative manufacturing facilities, which would delay our development program and significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacture of our product candidates or that obtained approvals could be revoked. Furthermore, CMOs may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate CMO or another acceptable solution in time, our clinical trials could be delayed, or our commercial activities could be harmed.

We rely on and will continue to rely on CMOs to purchase from third-party suppliers the raw materials necessary to produce our product candidates. We do not and will not have control over the process or timing of the acquisition of these raw materials by our CMOs. Moreover, we currently do not have any agreements for the production of these raw materials. Supplies of raw material could be interrupted from time to time and we cannot be certain that alternative supplies could be obtained within a reasonable timeframe, at an acceptable cost, or at all. In addition, a disruption in the supply of raw materials could delay the commercial launch of our product candidates, if approved, or result in a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates. Growth in the costs and expenses of raw materials may also impair our ability to cost effectively manufacture our product candidates. There are a limited number of suppliers for the raw materials that we may use to manufacture our product candidates and we may need to assess alternative suppliers to prevent a possible disruption of the manufacture of our product candidates.

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we generally have not, and do not intend to, begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates.

As part of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes the proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for or commercialize our product candidates, if approved.

Any performance failure or regulatory noncompliance on the part of CMOs could delay clinical development or marketing approval of our current in-development products or any future product candidates or commercialization of such product candidates, resulting in additional losses, and depriving us of potential product revenue.

Our reliance on single-sourced third parties to manufacture our product candidates increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of clinical or commercial supplies of the product candidates that we are developing or evaluating, nor are we contemplating plans to do so. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on third parties, such as Fisher Clinical Services for drug supply and drug product manufacture of our current product candidate, and our strategy is to continue to outsource all manufacturing of our product candidates and approved products, if any, to third parties.

In order to conduct clinical trials of our product candidates and prepare for commercialization, we will need to identify suitable manufacturers with the capabilities to manufacture our compounds in large quantities in a manner consistent with existing regulations. Our future plans include the identifying, qualifying, and contracting with a U.S. manufacturing site to manufacture ENV 105, assuming we have adequate financial resources to pursue contingency manufacturing plans. Our current and future third-party manufacturers may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities at any other time. If our manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

We do not currently have any agreements with third-party manufacturers for the long-term commercial supply of our current in-development products or any of our future product candidates. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of such product candidates or may be unable to do so on acceptable terms.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails risks, including:

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

Third-party manufacturers may not be able to comply with current Good Manufacturing Practice, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including 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 product candidates.

Our current in-development products and our future products and product candidates may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

If the third parties that we engage to supply any materials or manufacture product for our preclinical and nonclinical studies and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these studies and trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our current in-development products or any future product candidates or the substances used to manufacture them, it will be more difficult for us to develop such product candidates and compete effectively.

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

We intend to continue to rely on third parties to conduct, supervise and monitor our clinical trials. If those third parties do not successfully carry out their contractual duties, or if they perform in an unsatisfactory manner, it may harm our business.

We rely, and will continue to rely, on CROs, CRO-contracted vendors and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including our Phase 2 trials. Our reliance on CROs for clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards.

We and our CROs will be required to comply with the good laboratory practice requirements for our preclinical studies and GCP requirements for our clinical trials, which are regulations and guidelines enforced by the FDA and are also required by comparable foreign regulatory authorities. Regulatory authorities enforce GCP requirements through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. Accordingly, if our CROs fail to comply with these requirements, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our clinical trials. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, 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 any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationship with any CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

The number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers and the loss of, or a disruption in our relationship with, any one or more collaborators could harm our business.

If any collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research and development funding or milestone or royalty payments under such collaborations. If we do not receive the funding we expect under these agreements, our continued development of our product candidates could be delayed, and we may need additional resources to develop additional product candidates. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report also apply to the activities of any collaborators and there can be no assurance that our collaborations will produce positive results or successful products on a timely basis or at all.

In addition, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination or otherwise changes its business priorities, the collaborator might deemphasize or terminate the development or commercialization of our product candidates. If a collaborator terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of our business and our stock price could be adversely affected.

We may in the future collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to 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. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay 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, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. 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 or continue to develop our programs, and our business may be materially and adversely affected.

We are relying exclusively on the skills and expertise of our management team in conducting our business, not all of whom will devote all of their time to managing the Company, and we currently only have one full-time employee, which may impede our ability to carry on our business.

We are relying exclusively on the skills and expertise of our management team in conducting our business. Not all of our management team presently devotes all of their time to managing the Company. While our Chief Financial Officer serves on a full-time basis, we have no other full-time employees, which may impede our ability to carry on our business. The lack of full-time employees among our officers may very well prevent the Company's operations from being efficient, and may impair the business progress and growth, which is a risk to any investor. Our lack of full-time management may be an impediment to our business development. Without full-time officers, aside from our Chief Financial Officer, we may not have sufficient time and effort devoted to our commercialization efforts, or efforts to find and raise additional capital, or manage our business, which could impair our ability to succeed in our business plan and could cause investment in our Company to lose value.

We operate with a small team and our future success depends on our ability to retain key executives and to attract, retain, and motivate qualified personnel.

Our future success depends on our ability to retain our key officers and employees and to attract, retain and motivate highly qualified management and scientific personnel.

We currently have limited personnel. As of the date of this Annual Report, we had three part-time employees, including our Chief Executive officer, and our Chief Financial Officer was our only full-time employee. We are highly dependent on the management, research and development, clinical, financial and business development expertise of Dr. Yu and Dr. Bhowmick. Each of them may currently terminate their employments with us at any time. We do not maintain "key person" insurance for any of our executives or employees.

We will need to attract, hire and retain qualified officers and employees to achieve the Company's objectives. Recruiting and retaining qualified scientific personnel and sales and marketing personnel will be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among pharmaceutical, biotechnology and diagnostic companies for similar personnel. Furthermore, current officers or employees may decide to leave the Company, and current or former officers or employees may decide to sue the Company for owed but unpaid compensation. The loss of any of these persons' expertise would be difficult to replace and could have a material adverse effect on our ability to achieve our business goals.

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

We face substantial competition from large, well-funded, and experienced competitors, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. The immuno-oncology segment of the industry is in particular highly competitive. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical, and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions. Regardless of the degree of success in development of our technology, the Company faces competition from much larger enterprises and different technologies, disadvantages inherent in attempting to negotiate licensing or other transactions with companies with vastly larger financial, scientific and other resources, lack of management experienced in commercial business operations, reliance on contract laboratories and other third party service providers, lack of financial and other resources, challenges to the validity of intellectual property, potential product liabilities, and regulatory risks including product and reimbursement permits and regulations. Many of our competitors and potential competitors have substantially greater financial, technological, managerial and research and development resources and experience than we do. We are aware of other products under development, which, if successfully developed and commercialized, would compete with our products. We may be unable to keep pace with the rapid technological changes in the biotechnology/medical device industry and as a result, our technologies may become obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize medicines that are safer, are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any medicines we may develop. Our competitors also may obtain FDA or other regulatory approval for their medicines more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic medicines.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

In connection with the preparation of our financial statements, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses are as follows:

- We did not design and maintain an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked a sufficient complement of resources with (i) an appropriate level of accounting knowledge, experience and training to appropriately analyze, record and disclose accounting matters timely and accurately, and (ii) an appropriate level of knowledge and experience to establish effective processes and controls. Additionally, the lack of a sufficient number of professionals resulted in an inability to consistently establish appropriate authorities and responsibilities in pursuit of our financial reporting objectives, as demonstrated by, among other things, insufficient segregation of duties in our finance and accounting functions. This material weakness contributed to the following additional material weaknesses.
- We did not design and maintain effective controls related to the period-end financial reporting process, including designing and maintaining formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures. Additionally, we did not design and maintain controls over the preparation and review of account reconciliations and journal entries, including maintaining appropriate segregation of duties.
- We did not design and maintain effective controls related to the accounting for certain non-routine or complex transactions, including the proper application of U.S. GAAP to such transactions.
- Additionally, these material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.
- We did not design and maintain effective controls over information technology, or IT, general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain (i) program change management controls to ensure that information technology program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately, (ii) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs, and data to appropriate Company personnel, (iii) computer operations controls to ensure that critical batch jobs are monitored and data backups are authorized and monitored, and (iv) testing and approval controls for program development to ensure that new software development is aligned with business and IT requirements.

These IT deficiencies did not result in adjustments to the financial statements. However, the IT deficiencies, when aggregated, could impact maintaining effective segregation of duties, as well as the effectiveness of IT-dependent controls (such as automated controls that address the risk of material misstatement to one or more assertions, along with the IT controls and underlying data that support the effectiveness of system-generated data and reports) that could result in misstatements potentially impacting all financial statement accounts and disclosures that would not be prevented or detected. Accordingly, management has determined the IT deficiencies in the aggregate constitute a material weakness.

To address our material weaknesses, we are in the process of implementing measures designed to improve our internal control over financial reporting and remediate the control deficiencies that led to the material weaknesses. These measures include (i) the ongoing hiring of additional accounting personnel; (ii), initiating design and implementation of our financial control environment, including the establishment of formal accounting policies and procedures, financial reporting controls and controls to account for and disclose complex transactions; and (iii) initiating and designing IT controls to insure appropriate and restricted access to our accounting applications, programs, and data.

We are working to remediate the material weaknesses as efficiently and effectively as possible. We cannot assure you that there will not be future material weaknesses in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. If we fail to remediate our identified material weaknesses, or identify additional material weaknesses, in our internal control over financial reporting investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the exchange we are listed on, the NYSE American, the Securities and Exchange Commission, or SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

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

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary drug products, intellectual property rights, technologies, or businesses, as deemed appropriate to carry out our business plan. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;

- assimilation of operations, intellectual property, and drug products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing drug programs and initiatives in pursuing such a strategic partnership, merger, or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or drugs sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

Risks Related to Our Intellectual Property

Our exclusive licensing rights to our intellectual property are subject to agreements with third parties and we may not meet milestones set forth in those agreements; our exclusive licensing rights may be terminated.

Our agreements with Cedars-Sinai Medical Center and Tracon Pharmaceuticals, Inc., which were originally between each of Cedars-Sinai and Tracon and our subsidiary, Enviro Therapeutics, Inc., and which were assumed by the Company effective April 17, 2025 pursuant to a novation agreement, are contingent on our ability to make payments and meet commercialization goals, which we may not be able to meet based on innumerable factors. If we do not make such payments or meet such milestones, our exclusive licensing rights to our intellectual property may be terminated. Even if we meet certain milestones, we may not be able to make the required payments, which may cause us to breach such agreements.

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

We do not own any issued patents and we in-license patents and patent applications for ENV 105, our lead drug compounds, and our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to ENV 105 and any of our future product candidates. We seek to protect our proprietary position by in-licensing intellectual property relating to our product candidates including patent applications in the United States and abroad related to our technology and product candidates that are important to our business. If we or our licensors do not adequately protect the intellectual property, we in-license or own, competitors may be able to use our technologies and erode or negate any competitive advantage that we may have, which could harm our business and ability to achieve profitability. To protect our proprietary positions, we and our licensors file patent applications in the United States and abroad related to our novel technologies and product candidates that are important to our business. The patent application and prosecution process is expensive and time-consuming. We and our current licensors and licensees, or any future licensors and licensees may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We or our current licensors and licensees, or any future licensors or licensees may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection or fail to continue to prosecute patents relating to our product candidates. Therefore, these and any of our in-licensed patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our licensors' patents or our patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope, or patent term adjustments. If our current licensors and licensees, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using, and selling competing products. We cannot predict whether the patent applications we and our licensors or licensees are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. If there are material defects in the form or preparation of our or our licensors' patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how and we may not be able to prevent such competitors from commercializing such equivalent knowledge, methods, and know-how. Any of these outcomes could impair our ability to prevent competition from third parties and could have a material adverse effect on our business, financial condition, results of operations, or prospects. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and has been the subject of much litigation in recent years. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to pharmaceutical compounds and technologies commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Furthermore, recent changes in patent laws in the United States, including the America Invents Act of 2011, and future changes in patent laws in or outside the United States may affect the scope, strength, and enforceability of our patent rights or the nature of proceedings that may be brought by us related to our patent rights.

We may not be aware of all third-party intellectual property rights potentially relating to our current in-development products or our future product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in patents or pending patent applications that we in-license or own, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, and commercial value of our patent rights cannot be predicted with any certainty. Moreover, we or our licensors may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review, or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or product candidates, and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights.

Our licensors' pending and future patent applications and our own pending and future patent applications may not result in patents being issued that protect our technology or product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Even if our or our licensors' patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection against competing products or processes sufficient to achieve our business objectives, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our in-licensed patents or any patents we may own in the future by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated NDAs to the FDA in which they claim that patents licensed by us or may be owned by us in the future are invalid, unenforceable, and/or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend and/or assert our in-licensed or owned patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court, or other agency with jurisdiction may find our in-licensed patents or any owned patents, should such patents issue in the future, invalid and/or unenforceable.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our in-licensed patents or patents we may own in the future may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. 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. Any impairment of our intellectual property rights, or our failure to protect our intellectual property rights adequately, could give third parties access to our technology and product candidates and could materially and adversely impact our business, financial condition, results of operations, and prospects.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of cyber security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruptions of our operations. For example, the loss of preclinical data or data from any future clinical trial involving our product candidates could result in delays in our development and regulatory filing efforts and significantly increase our costs. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed.

Our proprietary information, or that of our customers, suppliers and business partners, may be lost or we may suffer security breaches.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Although to our knowledge we have not experienced any such material security breach to date, any such breach could compromise our network, or the networks of our CROs or other third-party service providers, and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, disrupt our operations, damage our reputation, and cause a loss of confidence in our products and our ability to conduct clinical trials, which could adversely affect our business and reputation and lead to delays in gaining regulatory approvals for our drugs.

Our rights to develop and commercialize our technology, our current in-development products, and our other future product candidates are subject, in large part, to the terms and conditions of licenses granted to us by others, such as Cedars-Sinai Medical Center and Tracon Pharmaceuticals, Inc. If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to products, technology, or data from third parties, we could lose such rights that are important to our business.

We are heavily reliant upon licenses to certain patent rights and other intellectual property that are important or necessary to the development of our current in-development products or our future product candidates. For example, we depend on license agreements from Cedars-Sinai Medical Center and Tracon Pharmaceuticals, Inc.

Cedars-Sinai and Tracon have relied upon, and any future licensors may have relied upon, third-party companies, consultants or collaborators, or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. We have sublicensed certain patents from Cedars-Sinai and Tracon. If third-party institutions such as Cedars-Sinai or Tracon fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize our current in-development products or our other future product candidates that are the subject of such licensed rights could be adversely affected. Further development and commercialization of ENV 105, and development of any future product candidates may, require us to enter into additional license or collaboration agreements. For example, our licensors or other third parties may develop intellectual property covering ENV 105 which we have not licensed. Our future licenses may not provide us with exclusive rights to use the licensed patent rights and other intellectual property or may not provide us with exclusive rights to use such patent rights and intellectual property in all relevant fields of use and in all territories in which we wish to develop or commercialize our current in-development products or our future product candidates in the future.

Our license agreements with Cedars-Sinai and Tracon, and other intellectual property-related agreements we may enter into in the future may impose diligence and other obligations, including payment of milestones and royalties. For example, our license agreement from Cedars requires us to satisfy diligence requirements, including using commercially reasonable efforts to develop and commercialize products. If we fail to comply with our obligations to our present or future licensors, those counterparties may have the right to terminate the license agreements, in which event we might not be able to develop, manufacture, or market any product candidate licensed under the agreements, which could materially adversely affect the value of the product candidate being developed under any such agreement and further involve termination of our rights to important intellectual property or technology.

In spite of our efforts, Cedars-Sinai, Tracon or any future licensors might conclude that we are in material breach of obligations under our license agreements and may therefore have the right to terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by such license agreements. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors would have the freedom to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in-licenses could prevent us from commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. 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 (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Under our license agreements with Cedars-Sinai and Tracon, and any future license agreements, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the license agreements involving 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 prevent or impair our ability to maintain our current 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.

We may not be successful in obtaining necessary rights to any product candidates we may develop through acquisitions and in-licenses.

We currently have rights to intellectual property, through licenses from third parties, to identify and develop product candidates. We may find it necessary or prudent to obtain licenses from such third-party intellectual property holders in order to avoid infringing these third-party patents. For example, many pharmaceutical companies, biotechnology companies, and academic institutions compete with us and may be filing patent applications potentially relevant to our business. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These 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 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 have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Competitors or other third parties may infringe, misappropriate or otherwise violate our in-licensed issued patents or our other intellectual property we may own. To counter such infringement, misappropriation, or other unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against third parties could provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their patents, trademarks, copyrights, or other intellectual property. In addition, our in-licensed patents may become involved in inventorship or priority disputes. Third parties may raise challenges to the validity of certain of our or our in-licensed patent claims and may in the future raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in derivation, revocation, reexamination, post-grant review, or PGR, *inter partes* review, or IPR, interference proceedings, and equivalent proceedings in foreign jurisdictions, such as opposition proceedings challenging any patents that we may own or in-license. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. A third party may also claim that our potential future owned patents or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, invalidate, or render unenforceable, our potential future owned patents or licensed patent rights, allow third parties to commercialize our current in-development products or our other future product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights In a patent infringement proceeding, there is a risk that a court will decide that a patent we in-license is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents are upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our in-licensed patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our in-licensed patents could limit our ability to assert our in-licensed patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, in the future, we expect to rely on trademarks to distinguish our current in-development products and any of our other future product candidates that are approved for marketing, and if we assert trademark infringement claims, a court may determine that the marks 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.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. 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 during litigation. In addition, there could be public announcements of the results of hearings, motions, or 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. Moreover, there can be no assurance that we will have sufficient financial or other resources to adequately file and pursue such infringement claims, which typically last for years before they are concluded. Some of our competitors and other third parties 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. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating, or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a negative impact on our ability to compete in the marketplace, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third parties may initiate legal proceedings alleging that we are infringing misappropriating, or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could significantly harm our business.

Our commercial success depends, in part, on our ability to develop, manufacture, market, and sell our current in-development products or other future product candidates and use our proprietary chemistry technology without infringing, misappropriating or otherwise violating the intellectual property of third parties. Numerous third-party U.S. and non-U.S. issued patents exist in the area of cancer therapies and other therapies our drugs are targeted to treat.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation, or other adversarial proceedings regarding intellectual property rights with respect to our technology or product candidates, including interference proceedings before the USPTO. Third parties may assert claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance.

If we are found to have infringed, misappropriated, or otherwise violated any third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing, or commercializing our current in-development products or other future product candidates. Alternatively, we may be required to obtain a license from such third party in order to use technology and continue developing, manufacturing or marketing product candidates that infringe or violate such third party's intellectual property. However, we may not be able to obtain any such required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We may also be required to pay substantial ongoing royalty or license payments, fees, or comply with other unfavorable terms. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement could prevent us from commercializing our current in-development products or other future product candidates or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative effect on our business. Even if we were to prevail in such a dispute, any litigation regarding our intellectual property could be costly and time-consuming and divert the attention of our management and key personnel from our business operations. 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 during this type of litigation. During the court of litigation, there could be public announcements or the results of hearings, motions, or other interim proceedings or developments. 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. Negative publicity related to a decision by us to initiate such enforcement actions against a customer or former customer, regardless of its accuracy, may adversely impact our other customer relationships or prospective customer relationships, harm our brand and business and could cause the market price of our common stock to decline. Any of the foregoing arising from uncertainty in legal proceedings could materially and adversely impact our business, financial condition, results of operations, and prospects.

We may be subject to claims by third parties asserting that we or our employees, consultants, and advisors have misappropriated their ***intellectual property or claiming ownership of what we regard as our own intellectual property.***

Many of our employees, consultants, and advisors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors do not use the proprietary information or know-how of third parties in their work for us, we may be subject to claims that we or such employees, consultants, and advisors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also in the future be subject to claims that we have caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these potential claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, such employees and contractors may breach the agreement and claim the developed intellectual property as their own. Further, we may be unsuccessful in executing such agreements with each party who, in fact, conceives, or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A court could prohibit us from using technologies or features that are essential to our current in-development products or other future product candidates if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and could be a distraction to management. In addition, any litigation or threat thereof may adversely affect our ability to hire employees or contract with independent service providers. Moreover, a loss of key personnel or their work product could hamper or prevent our ability to commercialize our product candidates. Any of the foregoing could have a material adverse impact on our business, financial condition, results of operations, and prospects.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our* products.**

As is the case with other pharmaceutical companies, our success is heavily dependent on our intellectual property rights, and particularly on our in-licensed patent rights. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity, and is therefore costly, time consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. Certain U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain rights to patents in the future, this combination of events has created uncertainty with respect to the value of patents once rights are obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could further negatively impact the value of patent rights, narrow the scope of available patent protection or weaken the rights of patent owners.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. We have not yet selected trademarks for our product candidates and have not yet begun the process of applying to register trademarks for our product candidates. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties who have prior rights to our trademarks or third parties who have prior rights to similar trademarks may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our product candidates, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby diluting or impeding our ability to build brand identity and possibly leading to market confusion. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks and may not be able to prevent such third parties from using and marketing any such trademarks.

In addition, any proprietary name we propose to use with our current in-development products or any future product candidate 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. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively and our business, financial condition, results of operations, and prospects may be adversely affected.

If we are unable to protect the confidentiality of our proprietary information, know-how, and trade secrets, the value of our current in-development products or other future product candidates could be adversely affected, and our business and competitive position would be harmed.

In addition to seeking patent protection for our current in-development products or other future product candidates, we also rely on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these agreements may be inadequate to protect our proprietary and intellectual property rights. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets. In addition, we may not be able to obtain adequate remedies for any such breaches. Although we use reasonable efforts to protect this proprietary information and technology, we also cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information, know-how, trade secrets, or other proprietary information or each individual who has developed intellectual property on our behalf. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, distracting to management, and time-consuming, and the outcome is unpredictable and varied depending on the jurisdiction. In addition, some courts inside and outside the United States, in countries in which we operate or intend to operate, are less willing, or unwilling, to protect trade secrets, know-how, and other proprietary information. Any claims or litigation could cause us to incur significant expenses. Some third parties may be able to sustain the costs of complex litigation more effectively than we can because they have substantially greater resources.

Our employees, consultants, and other parties may unintentionally or willfully disclose our information or technology to competitors and there can be no assurance that the legal protections and precaution taken by us will be adequate to prevent misappropriation of our technology or that competitors will not independently develop technologies equivalent or superior to ours. Trade secrets and know-how can be difficult to protect. Our competitors or other third parties may independently develop knowledge, methods and know-how equivalent to our trade secrets. Additionally, competitors could purchase our product candidates and replicate some or all of the competitive advantages we derive from our development efforts for technologies on which we do not have patent protection. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we or our licensors do not obtain patent term extension and data exclusivity for any product candidates we or our licensors may develop, our business may be materially harmed.

Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents we license or may own in the future 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 our product candidates. Depending upon the timing, duration, and specifics of any FDA marketing approval of any of our product candidates, one or more of our in-licensed U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for 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 product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government 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 government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned or in-licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government agencies require compliance with several 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. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could 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 licensed 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, even in jurisdictions where we or our licensors do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our in-licensed inventions in all countries outside the United States, even in jurisdictions where our licensors do pursue patent protection or from selling or importing products made using our inventions in and into the United States or other jurisdictions.

Competitors may use our technologies in jurisdictions where we or 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 current in-development products, our future product candidates, and our preclinical programs. Our in-licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our in-licensed patents, if pursued and obtained, or the marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our in-licensed patents at risk of being invalidated or interpreted narrowly and our in-licensed patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. 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.

Many 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. In these countries, the patent owner may have limited remedies, 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 patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

Risks Related to Healthcare Laws and Other Legal Compliance Matters

If we successfully commercialize our current in-development products or one of our future product candidates, failure to comply with our reporting and payment obligations under U.S. governmental pricing programs could have a material adverse effect on our business, financial condition, and results of operations.

If we participate in the Medicaid Drug Rebate Program, Part D, if and when we successfully commercialize a product candidate, we will be required to report certain pricing information for such product candidate to the Centers for Medicare & Medicaid Services, the federal agency that administers the Medicaid and Medicare programs. We may also be required to report pricing information to the U.S. Department of Veterans Affairs. If we become subject to these reporting requirements, we will be liable for errors associated with our submission of pricing data, for failure to report pricing data in a timely manner, and for overcharging government payers, which can result in civil monetary penalties under the Medicaid statute, the federal civil False Claims Act, and other laws and regulations.

Our current and future relationships with healthcare professionals, principal investigators, consultants, customers, and third-party payors in the United States and elsewhere may be 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 penalties.

Healthcare providers, physicians, 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 marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers, and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we research, sell, market, and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security 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 that may affect our ability to operate include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid;

- federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

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

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of whether the payor is public or private, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" and their respective subcontractors that create, receive, maintain, or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, created under Section 6002 of Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, and its implementing regulations, created annual reporting requirements for manufacturers of drugs, devices, biologicals, and medical supplies for certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. As of January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners; and

- analogous state and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign 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 or to adopt compliance programs as prescribed by state laws and regulations, or that otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws requiring the licensure of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Further, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, including, without limitation, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare 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 and pursue our strategy. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including future collaborators, are found not to be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from participation in government healthcare programs, which could also affect our business.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been Congressional inquiries and proposed federal and state legislation designed to bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Changes in healthcare policies, laws, and regulations may impact our ability to obtain approval for, or commercialize our current in-development products or our future product candidates, if approved.

In the United States and some foreign jurisdictions there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system in an effort to contain costs, improve quality, and expand access to care. In the United States, there have been and continue to be a number of healthcare-related legislative initiatives, as well as executive, judicial, and Congressional challenges to existing healthcare laws that have significantly affected, and could continue to significantly affect, the healthcare industry. 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. Thus, the Affordable Care Act will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. 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. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs and review the relationship between pricing and manufacturer patient programs. Further, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our current in-development products or our future product candidates or additional pricing pressures.

We are subject to privacy and data security laws, rules, regulations, policies, industry standards, and contractual obligations, and our failure to comply with them could harm our business.

We maintain a large quantity of sensitive information, including confidential business information and information related to our employees and we expect to maintain personal information in connection with the conduct of our clinical trials. As such, we are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure, and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and is expected to increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, including Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA.

Compliance with these and any other applicable privacy and data security laws and regulations we may be subject to in the future is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition, results of operations or prospects. Any failure by us or our third-party processors to comply with these data protection and privacy laws and regulations could result in significant government enforcement actions, which could include civil, criminal, and administrative penalties, orders requiring that we change our practices, claims for damages, and other liabilities, regulatory investigations and enforcement action, private litigation, significant costs of remediation, and adverse publicity, any of which could negatively affect our operating results and business. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements.

With laws, regulations, and other obligations relating to privacy and data protection 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 protection laws and regulations. We do not currently have any formal data privacy policies and procedures in place and have not completed formal assessments of whether we are in compliance with all applicable data privacy laws and regulations. Additionally, if third parties with which we work, such as vendors or 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 data, at risk, and our business, financial condition, results of operations, and prospects may be adversely affected.

Any clinical trial programs we conduct or research collaborations we enter into in the European Economic Area may subject us to the General Data Protection Regulation.

If we conduct clinical trial programs or enter into research collaborations in the European Economic Area, or EEA, we may be subject to the General Data Protection regulation, or GDPR. The GDPR applies extraterritorially and implements stringent operational requirements for processors and controllers of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data, robust disclosures to individuals, a comprehensive individual data rights regime, data export restrictions governing transfers of data from the EEA/European Union, or EU, to other jurisdictions, short timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data, other special categories of personal data and coded data and additional obligations if we contract third-party processors in connection with the processing of personal data. The United Kingdom has implemented its own version of the GDPR, which contains similar requirements. The GDPR provides that EU member states may establish their own laws and regulations limiting the processing of personal data, including genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs to increase. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

Our product candidates may be subject to government price controls that may affect our revenue.

There has been heightened governmental scrutiny in the United States and abroad of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. In the United States, such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the state level, legislatures have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological 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. Outside of the United States, particularly in the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our current in-development products or our future product candidates to other available therapies. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed.

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

We are subject to numerous environmental, health, and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment, and disposal of hazardous materials and wastes. Our operations involve the use of hazardous materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from 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 for failure to comply with such laws and regulations.

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

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

We are subject to U.S. and certain 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 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 may engage third parties to sell our current in-development products or our future product candidates outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. 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.

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates or any other product candidates that we may develop in the future.

We rely, and will rely, on third-party CROs, study sites and others to conduct, supervise, and monitor our preclinical studies and clinical trials for our product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to support future approval of our product candidates, or we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, our product development activities would be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical trials are conducted in accordance with the FDA's Good Laboratory Practice (GLP) regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as GCP guidelines, for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions. For example, the data generated in our trials may not have been appropriately collected or documented, and thereby be deemed unreliable and the FDA or comparable foreign regulatory authorities may conclude the study findings are not adequate and require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our trials complies with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on one or more government-sponsored databases, e.g., ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not 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, non-clinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates; or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We will also rely on other third parties to store and distribute our product candidates for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of our product candidates, which could result in additional losses and deprive us of potential product revenue.

We have entered into, and may in the future enter into, certain collaboration agreements and strategic alliances to maximize the potential of our product candidates, and we may not realize the anticipated benefits of such collaborations or alliances. We expect to continue to form collaborations in the future with respect to our product candidates, but may be unable to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

We may form or seek other strategic alliances, 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 product candidates we develop. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or other anticipated benefits that led us to enter into the arrangement. Additionally, the success of any collaboration arrangements may depend on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

If we are not able to establish future collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans for one or more of our other development programs.

We face significant competition in seeking appropriate additional collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay 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, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. 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 or continue to develop our product platform and our business may be materially and adversely affected.

Our current and any future collaborations are not a guarantee of success, and all collaborations are as risky, or riskier, than undertaking the activities ourselves.

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or us to regulatory enforcement actions;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; and
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

In addition, all of the risks relating to product development, regulatory approval and commercialization described in this Annual Report also apply to the activities of any of our current or future collaborators.

Collaborations with biopharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

If any collaborations we have entered into or might enter into do not result in the successful development and commercialization of products or if one of our collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates and our product platform.

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

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay 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, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. 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 or continue to develop our product platform and our business may be materially and adversely affected.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency 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.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, 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. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, the FDA and regulatory authorities outside the United States have and may adopt restrictions or other policy measures in response to the COVID-19 pandemic that divert resources and delay their attention to any submissions we may make. If a prolonged government shutdown occurs, or if global health concerns continue to 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.

Risks Related to Commercialization of Our Products

There is no assurance that we will be able to obtain FDA approval and, even if we do, there is no assurance that either we, or our collaboration partners, will be successful in commercializing any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.

Even if we obtain FDA approval, there is no assurance that we, or our collaboration partners, will be successful in obtaining marketing approval from applicable regulatory authorities for ENV 105 or any other product candidate. Our ability to generate revenues from any such products will depend on our success in:

- Successfully completing our Phase 1 and Phase 2 clinical trials and obtaining FDA approval for our product candidates;
- launching commercial sales of such products, whether alone or in collaboration with others;
- receiving approved labels with claims that are necessary or desirable for successful marketing, and that do not contain safety or other limitations that would impede our ability to market such products;
- creating market demand for such products through marketing, sales and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize such products in the United States;
- creating partnerships with, or offering licenses to, third parties to promote and sell such products in foreign markets where we receive marketing approval;
- manufacturing such products in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- maintaining patent and trade secret protection and regulatory exclusivity for such products;
- achieving market acceptance of such products by patients, the medical community, and third-party payors;
- achieving coverage and adequate reimbursement from third-party payors for such products;
- achieving patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement from third-party payors;
- competing effectively with other therapies; and
- maintaining a continued acceptable safety profile of such products following launch.

To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.

The development and commercialization of cancer resistance products and immunotherapy products is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. 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.

While certain of our product candidates may be used in combination with other drugs with different mechanisms of action, if and when marketed they will still compete with a number of drugs that are currently marketed or in development that also target cancer. To compete effectively with these drugs, our product candidates will need to demonstrate advantages in clinical efficacy and safety compared to these competitors when used alone or in combination with other drugs.

Our commercial opportunities 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 easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies. Our competitors also may obtain FDA or comparable foreign regulatory authorities' 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 are able to enter the market. In addition, our ability to compete may be affected in many cases by third-party payors' coverage and reimbursement decisions.

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

If we are unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market and sell our product candidates, if they are approved, the revenues that we generate may be limited and we may never become profitable.

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of any products that we may develop. If and when our product candidates receive marketing approval, we intend to commercialize our product candidates on our own or in collaboration with others and potentially with pharmaceutical or biotechnology partners in other geographies. In order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so. Should we decide to move forward in developing our own marketing capabilities, we may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of the FDA or comparable foreign regulatory authority requirements or other reasons, we would incur these expenses prior to being able to realize any revenue from sales of our product candidates. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our product candidates. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may also or alternatively decide to collaborate with third-party marketing and sales organizations to commercialize any approved product candidates, in which event, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other biopharmaceutical and biotechnology companies, including oncology-focused companies, to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development.

In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize our product candidates, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, stock price and prospects. Factors that may inhibit our efforts to commercialize our product candidates include:

- the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing our product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training personnel, including sales and marketing personnel, on compliance matters and monitoring their actions;
- an inability to secure coverage and adequate reimbursement by third-party payors, including government and private health plans;
- the unwillingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement from third-party payors;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for our personnel, including sales or marketing personnel, who fail to comply with applicable law;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community necessary for commercial success. The revenues that we generate from their sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval does not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. Market acceptance of our product candidates by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any product for which we receive marketing approval will depend on a number of factors, including:

- the efficacy of our product, including in combination with other cancer therapies;
- the commercial success of any cancer therapies with which our product may be co-administered;
- the prevalence and severity of adverse events associated with our product or those products with which it is co-administered;
- the clinical indications for which our product is approved and the approved claims that we may make with respect to the product;
- limitations or warnings contained in the FDA-approved labeling of the product or the labeling approved by comparable foreign regulatory authorities, including potential limitations or warnings for our product that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our product, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of our product and any products with which it is co-administered;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of coverage and adequate reimbursement by third-party payors, such as private insurance companies and government healthcare programs, including Medicare and Medicaid;
- the ability to have our product placed on approved formularies;
- patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement from third-party payors;
- the price concessions required by third-party payors to obtain coverage and adequate reimbursement;
- the extent and strength of our marketing and distribution of our product;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our product or to which we agree as part of a REMS or voluntary risk management plan;
- the timing of market introduction of our product, as well as competitive products;
- our ability to offer our product for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our raw material supplier and service provider support;
- the actions of companies that market any products with which our product is co-administered;
- the approval of other new products;
- adverse publicity about our product or any products with which it is co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates. If the market opportunities for any product candidates we develop are smaller than we believe they are, our potential revenues may be adversely affected, and our business may suffer.

The potential market opportunities for our product candidates are difficult to estimate and will depend in large part on the drugs with which our product candidates are co-administered and the success of competing therapies and therapeutic approaches. In particular, the market opportunity for cancer resistance drugs is hard to estimate given that it is an emerging field. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. Our estimates of the potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. These estimates may prove to be incorrect and new studies may change the estimated incidence or prevalence of these diseases. The number of patients in the United States, Europe, and elsewhere may turn out to be lower than expected, and patients may not be amenable to treatment with our product. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities. Additionally, because of the potential that any product candidates we develop could cure a target disease, we may not receive recurring revenues from patients and may deplete the patient population prevalence through curative therapy.

Risks Related to Government Regulation

If we fail to comply with federal and state healthcare laws, including fraud and abuse laws, we could face substantial penalties and our business, financial condition, results of operations, stock price and prospects will be materially harmed.

Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable healthcare fraud and abuse, and other healthcare laws, which may constrain the business or financial arrangements and relationships through which we research, as well as sell, market and distribute any products for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, 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 a federal healthcare program, such as the Medicare and Medicaid programs.

- The federal civil and criminal false claims laws, including, without limitation, the civil FCA, and the federal Civil Monetary Penalties Law, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government.

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA), which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.

- The U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biological products and medical devices.

- The federal physician payment transparency requirements, sometimes referred to as the Physician Payments Sunshine Act, created under the ACA and its implementing regulations, which require certain manufacturers of drugs, devices, biological products and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), 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 state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or that apply regardless of payor; 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; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; and state and local laws requiring the registration of pharmaceutical sales representatives.

If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental laws or regulations that apply to us, we may be subject to penalties, including significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, imprisonment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in U.S. federal or state health care programs, additional reporting requirements and/or oversight if we become subject to corporate integrity agreements or similar agreement to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, it may be subject to significant criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in U.S. federal or state healthcare programs, which could also materially affect our business.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with such laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

If the government or third-party payors fail to provide adequate coverage, reimbursement and payment rates for our product candidates, or if health maintenance organizations or long-term care facilities choose to use therapies that are less expensive or considered a better value, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, sales of our products will depend in part upon the availability of coverage and adequate reimbursement from third-party payors or placement on approved product formularies. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers, and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new therapeutic products when more established or lower cost therapeutic alternatives are already available or subsequently become available, even if our products are alone in a class. Third-party payors establish reimbursement levels. Therefore, even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we may not be able to successfully commercialize our product candidates. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost. Our failure to obtain or maintain timely or adequate pricing or formulary placement of our products, or failure to obtain such formulary placement at favorable pricing may negatively impact our revenue.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved therapeutics. Marketing approvals, pricing, and reimbursement for new therapeutic products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a therapeutic before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues 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 our product candidates obtain marketing approval. Our ability to commercialize our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors.

A significant trend within the healthcare industry is cost containment, both in the United States and elsewhere. Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs, including use of formularies. Exclusion of a product from a formulary or other restrictions can significantly impact drug usage in the patient population and beyond. Consequently, pharmaceutical companies compete to gain access to formularies for their products, typically on the basis of unique product features, such as greater efficacy, better patient ease of use, or fewer side effects, as well as the overall cost of the therapy. Certain third-party payors are requiring that companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes, are disregarding therapeutic differentiators within classes, are challenging the prices charged for therapeutics, and are negotiating price concessions based on performance goals. In addition, third-party payors are increasingly requiring higher levels of evidence of the benefits and clinical outcomes of new technologies, benchmarking against other therapies, seeking performance-based discounts, and challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. If payors subject our product candidates to maximum payment amounts, or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may seek alternative therapies. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

In addition, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a negative effect on our business, financial condition, results of operations, stock price and prospects.

There may also be delays in obtaining coverage and reimbursement for newly approved therapeutics, and coverage may be more limited than the indications for which the product is approved by the FDA or comparable foreign regulatory authorities. Such delays have made it increasingly common for manufacturers to provide newly approved drugs to patients experiencing coverage delays or disruption at no cost for a limited period in order to ensure that patients are able to access the drug. Moreover, eligibility for reimbursement does not imply that any therapeutic will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new therapeutics, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost products or may be incorporated into existing payments for other services.

An inability to promptly obtain coverage and adequate reimbursement from third-party payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We are subject to new legislation, regulatory proposals and third-party payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators, and raise capital.

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

For example, the ACA was passed in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the United States pharmaceutical industry.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017 (the Tax Act), includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." 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. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period 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. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the 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 through a newly established 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 the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have been proposed and adopted in the United States since the ACA. For example, through the process created by the Budget Control Act of 2011, there are automatic reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2018 (BBA) and the Infrastructure Investment and Jobs Act, will remain in effect until 2031 unless additional Congressional action is taken.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the biopharmaceutical industry. For instance, the Drug Quality and Security Act of 2013 imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Further, manufacturers have product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences of death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Compliance with the federal track and trace requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

There has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biological products. Such scrutiny has resulted in presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products.

At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA concurrently released a final rule and guidance in September 2020, implementing a portion of the importation executive order providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health and Human Services (HHS) finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of the rule has been delayed until 2032. 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, 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. In addition, the IRA directs the Secretary of HHS to establish a Drug Price Negotiation Program (the Program) to lower prices for certain single-source prescription drugs and biologics covered under Medicare Parts B and D, based on criteria established under the IRA. Under the Program, the Secretary of HHS will publish a list of "selected drugs," and will then negotiate maximum fair prices (MFP) with their manufacturers. Beginning in 2026, the first year of the Program, the number will be limited to 10 Part D drugs and biologics. By 2029, and in subsequent years thereafter, the number will increase to 20 drugs and biologics covered under Part D and Part B. Agreements between HHS and manufacturers will remain in place until a drug or biologic is no longer considered a "selected drug" for negotiation purposes. Manufacturers who do not comply with the negotiated prices set under the Program will be subject to an excise tax based on a percentage of total sales of a "selected drug" up to 95% and the potential of civil monetary penalties. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological 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.

Any new laws or regulations, including those that may result in additional reductions in Medicare and other healthcare funding, could have a material adverse effect on customers for our products, if approved, and, accordingly, on our results of operations.

We expect that the ACA, as well as other federal and state healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our biopharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from commercializing our products and being able to generate revenue, and we could be prevented from or significantly delayed in achieving profitability.

We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as import and export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, and other consequences, which could adversely affect our business, financial condition, results of operations, stock price and prospects.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act (FCPA) and other anti-corruption laws that apply in countries where we do business. The FCPA and these other anti-corruption laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. We can be held liable for the corrupt or other illegal activities of our personnel or intermediaries, even if we do not explicitly authorize or have prior knowledge of such activities.

We are also subject to other laws and regulations governing our international operations, including applicable import and export control regulations, economic sanctions on countries and persons, anti-money laundering laws, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

We can provide no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws or other legal requirements, including trade control laws. If we are not in compliance with applicable anti-corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, stock price and prospects. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. An investigation of any potential violations of anti-corruption laws or trade control laws by U.S. or other authorities could also have an adverse impact on our reputation, our business, financial condition, results of operations, stock price and prospects.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, and patient information. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

We may be subject to or affected by evolving federal, state and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws (e.g. Section 5 of the Federal Trade Commission Act). For example, HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information or other personal information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA. While we do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly regulated under HIPAA, any person may be prosecuted under HIPAA's criminal provisions if it knowingly receives individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information under aiding-and-abetting or conspiracy principles.

Certain states have also adopted data privacy and security laws and regulations, which govern the privacy, processing and protection of health-related and other personal information. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act of 2018 (CCPA) imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation). Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. The California Privacy Rights Act of 2020 (CPRA), effective January 1, 2023, further expanded the CCPA in California by adding additional consumer rights and obligations for businesses. In addition, the CPRA established the California Privacy Protection Agency, which is tasked with CRPA implementation and enforcement, among other responsibilities. Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which became effective in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR), the United Kingdom's GDPR (UK GDPR), and the Swiss Federal Act on Data Protection impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals or consumer protection organizations authorized at law to represent their interests may initiate litigation related to processing of individuals' personal data.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, in addition to direct compliance obligations under those laws. We may be directly or contractually subject to data privacy and security obligations, including industry standards adopted by industry groups and may become subject to new data privacy and security obligations in the future. For example, certain privacy laws, such as the EU GDPR and the CCPA, require companies to impose specific contractual restrictions on their service providers. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, Europe has significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws.

Although there are currently various mechanisms that may be used to transfer personal data from Europe to the United States in compliance with law, such as the EU and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from Europe or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, which could limit our ability to conduct clinical trial activities in Europe or elsewhere, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have prevented companies from transferring personal data out of Europe for allegedly violating the GDPR and EU's cross-border data transfer limitations.

Obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. We may also be bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. Additionally, we publish privacy policies, self-certifications, and other documentation regarding our collection, use and disclosure of personal information and/or other confidential information. Although we endeavor to comply with our published policies, certifications, and documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations. Such failures can subject us to potential international, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other costs that could have a material adverse effect on the success of our business.

We are subject to numerous federal, state and local environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the controlled production, storage, use and disposal of hazardous and flammable materials, including chemicals and biological materials such as infectious agents and various radioactive compounds. We would incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third-party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, 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, as well as our curtailment of the use of these materials or even shutting down our facilities and operations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. While we maintain insurance covering our manufacturing facility only, and not our other facilities, for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials, such insurance coverage may not be sufficient to cover extraordinary or unanticipated events at our manufacturing facility.

Risks Related to Ownership of Our Common Stock

Future sales of our common stock, or the perception in the public markets that these sales may occur, could cause the market price for our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to the restrictions and limitations described below. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

We have reserved 1,650,000 shares of common stock for issuance under our 2023 Equity Incentive Plan, and we have issued a total of 80,000 restricted stock and/or restricted stocks to our independent directors and consultants. We cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock prevailing from time to time. Sales of substantial amounts of shares of our common stock in the public market, or the perception that those sales will occur, could cause the market price of our common stock to decline.

Such shares are registered on Form S-8 and will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Additionally, the holders of certain shares of our common stock, or their transferees, have rights, subject to certain conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of those shares, they could be freely sold in the public market without limitation. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Financings could adversely affect common stock ownership interest and rights in comparison with those of other security holders.

Our board of directors, in accordance with our Certificate of Incorporation and Bylaws, has the power to issue additional shares of common stock or preferred stock without stockholder approval. If additional funds are raised through the issuance of equity or convertible debt securities, the percentage ownership of our existing stockholders will be reduced, and these newly issued securities may have rights, preferences or privileges senior to those of existing stockholders.

Our board of directors may establish the rights, privileges, preferences and restrictions, including voting rights, of future series of stock and to issue such stock without approval from our shareholders. The rights of holders of common stock may suffer as a result of the rights granted to holders of preferred stock that may be issued in the future. In addition, we could issue preferred stock to prevent a change in control of our Company, depriving common shareholders of an opportunity to sell their stock at a price in excess of the prevailing market price.

If we issue any additional common stock or securities convertible into common stock, such issuance will reduce the proportionate ownership and voting power of each other stockholder. In addition, such stock issuances might result in a reduction of the per share book value of our common stock and result in what is more commonly known as dilution. We may issue further shares as consideration for the cash or assets or services out of our authorized but unissued common stock that would, upon issuance, represent a majority of the voting power and equity of our Company. The result of such an issuance would be those new stockholders and management would control our Company, and persons unknown could replace our management at that time. Such an occurrence would result in a greatly reduced percentage of ownership of our Company by our current stockholders, which could present significant risks to stockholders. The Company may raise capital in the futures in "down rounds" at a lower per share price than the trading price for our stock, which would be dilutive to prior investors, and there can be no assurance that future rounds will not be necessary that would be dilutive to investors in the current round. Investors may experience dilution in any future financing conducted by the Company.

We may not be able to maintain a listing of our common stock on NYSE American.

We must meet certain financial and liquidity criteria to maintain our listing on NYSE American. If we violate the listing requirements of such stock exchange, or if we fail to meet any of such exchange's continued 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 NYSE American 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 your investment.

If our shares of common stock become subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not maintain a listing on NYSE American or another national securities exchange and if the price of our common stock is less than $5.00, our common stock could be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

While we are not a controlled company, our chairman of the board of directors presently has control over key decision making as a result of his control of a majority of our voting stock and exercises significant voting power.

John S. Yu, our Chairman, and CEO, has the right to exercise voting rights with respect to an aggregate of 5,341,837 shares of common stock, which represents approximately 36.00% of the voting power of our outstanding capital stock. As a result, Dr. Yu has the ability to substantially control the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation, or sale of all or substantially all of our assets. This could delay, defer, or prevent a change of control, merger, consolidation, or sale of all or substantially all of our assets that our other stockholders support, or conversely this concentrated control could result in the consummation of such a transaction that our other stockholders do not support. This could also discourage a potential investor from acquiring our common stock due to the limited voting power of such stock relative to the shares of common stock and might harm the market price of our common stock. In addition, Dr. Yu has the ability to substantially control the management and major strategic investments of our Company as a result of his position as our CEO and his ability to control the election or replacement of our directors. In the event of his death, the shares of our capital stock that Dr. Yu owns will be transferred to the persons or entities that he designates. As a board member and officer, Dr. Yu owes a fiduciary duty to our stockholders and must act in good faith in a manner he reasonably believes to be in the best interests of our stockholders. As a stockholder, even a controlling stockholder, Dr. Yu is entitled to vote his shares in his own interests, which may not always be in the interests of our stockholders generally.

Concentration of ownership of our common stock among our existing executive officers, directors, and principal stockholders may prevent new investors from influencing significant corporate decisions and matters submitted to stockholders for approval.

As of the date of this Annual Report, our executive officers, directors, and current beneficial owners of 5% or more of our capital stock and their respective affiliates hold, in the aggregate, beneficially own 37.2% of our outstanding common stock, based on 21,411,198 shares of our common stock outstanding as of March 31, 2026. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, or sale of all or substantially all of our assets, or other significant corporate transactions. In addition, these persons, acting together, may have the ability to control the management and affairs of our Company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

- delaying, deferring, or preventing a change in control;
- entrenching our management and/or the board of directors;
- impeding a merger, consolidation, takeover, or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

In addition, some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price and have held their shares for a longer period, they may be more interested in selling our Company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our Company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition, or other change in control of our Company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66 2/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired more than 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our certificate of incorporation provides that unless we consent in writing to the selection of an alternative forum, and except for actions brought under the Securities Act or the Exchange Act, the Court of Chancery of the State of Delaware will be the exclusive forums for substantially all disputes between us and our stockholders. In addition, our exclusive forum provision may result in increased costs for investors to bring a claim.

Our certificate of incorporation provides that unless we consent in writing to the selection of an alternative forum, and except for actions brought under the Securities Act or the Exchange Act, the Court of Chancery of the State of Delaware is the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws;
- any action or proceeding to interpret, apply, enforce, or determine the validity of our certificate of incorporation, or our bylaws; and
- any action asserting a claim against us or any of our directors, officers, employees, or agents that is governed by the internal-affairs doctrine.

Any person purchasing or otherwise acquiring or holding any interest in shares of our capital stock is deemed to have received notice of and consented to the foregoing provisions. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds more favorable for disputes with us or with our directors, officers, other employees or agents, or our other stockholders, which may discourage such lawsuits against us and such other persons or may result in additional expense to a stockholder seeking to bring a claim against us. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, results of operations, financial condition, and prospects. In addition, our exclusive forum provision may result in increased costs for investors to bring a claim.

The choice of forum provision in our certificate of incorporation specifically excludes actions brought under the Securities Act or Exchange Act. Section 27 of 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 forum selection provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. 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.

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.

We will have broad discretion in the use of proceeds from selling of our securities and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

Our management will have broad discretion in the application of our cash, including the net proceeds from selling our securities, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a negative impact on our business, cause the price of our common stock to decline, and delay the development of our current in-development products and planned pipeline and expansion programs as well as commercial preparedness. Pending their use, we may invest our cash, including the net proceeds from our IPO and following equity offerings, in a manner that does not produce value or that loses value.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future, and accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility or debt securities may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. If we do not pay cash dividends, you could receive a return on your investment in our common stock only if you are able to sell your shares in the future and the market price of our common stock has increased when you sell your shares. As a result, investors seeking cash dividends should not purchase our common stock.

General Risk Factors

The trading price of our common stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock could be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their shares at or above the price paid for the shares. In addition to the factors discussed under this “Item1A Risk Factors” section and elsewhere in this Annul Report, these factors include:

- the commencement, enrollment, or results of our planned and future clinical trials;
- the loss of any of our key research, development, or management personnel;
- regulatory or legal changes or developments in the United States and other countries or in the status of our regulatory approvals;
- the success of competitive products or technologies;
- the emergence of new competitors or new technologies;
- our ability to develop and market new and enhanced products on a timely basis;
- adverse actions taken by regulatory agencies with respect to our clinical trials or manufacturers;
- changes or developments in laws or regulations applicable to our current in-development products or any future product candidates;

- changes to our relationships with collaborators, manufacturers, or suppliers;
- the results of our testing and clinical trials;
- disruption to our operations or those of other sources critical to our operations;
- unanticipated safety, tolerability, or efficacy concerns;
- announcements by us or our competitors of acquisitions, new products, significant contracts, commercial relationships or capital commitments;
- other announcements concerning our competitors or the pharmaceutical industry in general;
- actual or anticipated fluctuations in our operating results or those of our competitors;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions;
- the results of our efforts to discover, develop, acquire, or in-license additional product candidates;
- commencement of, or our involvement in, litigation;
- dilutive issuances of our stock or the stock of our subsidiaries, or the incurrence of additional debt;
- changes in our board of directors or management;
- adoption of new or different accounting standards;
- the trading volume of our common stock on NYSE American;
- sales of our common stock by us, our executive officers and directors or our stockholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States or the United Kingdom (including those relating to macroeconomic events, such as wars in the Middle East and between Russia and Ukraine);
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- general economic conditions and slow or negative growth of related markets; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares of our common stock at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation.

Any lawsuit to which we are a party, regardless of merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices.

Any lawsuit to which we are a party, regardless of the merit of such lawsuit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions, or other interim proceedings or developments, which could have a negative effect on the market price of our common stock.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business, or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our shares could decrease, which in turn could cause the trading price or trading volume of our common stock to decline.

We incur significantly costs as a result of operating as a company whose common stock is publicly traded in the United States, and our management are required to devote substantial time to new compliance initiatives.

As a public company in the United States, we incur significant legal, accounting, and other expenses. These expenses will likely be even more significant after we no longer qualify as an emerging growth company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of NYSE American, and other applicable securities rules and regulations impose various requirements on public companies in the United States, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will 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, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

However, 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.

Pursuant to Section 404, public companies are required to furnish a report by our senior management on our internal control over financial reporting. However, as we are presently an emerging growth company, so long as we remain in the status, or up to five years, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. At such time as we will be required to prepare for eventual compliance with Section 404, we will be required to engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. Identifying material weaknesses could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business, and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process, and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information, and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity, and restricted availability of such sensitive information. We have also outsourced elements of our operations, including elements of our information technology infrastructure, to third parties and, as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to other third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks, and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious, internal, and external attacks on our technology environment. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication, and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states, and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our or our third-party vendors' or business partners' information technology systems or other similar data security incidents could adversely affect our business operations and result in the loss, misappropriation, and unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business, and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war, and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from ongoing, completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We cannot ensure that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties with which we work, will prevent breakdowns or breaches in our or their systems or other cybersecurity incidents that cause loss, destruction, unavailability, alteration, dissemination of, or damage, or unauthorized access to, our data, including personal data, assets, and other data processed or maintained on our behalf, that could have a material adverse effect upon our reputation, business, operations, or financial condition.

While we have implemented security measures intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents. There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and state breach notification laws and foreign law equivalents, subject us to time-consuming, distracting, and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations, and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us, and result in significant legal and financial exposure and reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality, or data security-related legal or other obligations to third parties, or any further security incidents or other inappropriate access events, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators, or current and potential partners, to lose trust in us, or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Any of the foregoing could have a material adverse effect on our reputation, business, operations, or financial condition.

We are an "emerging growth company" and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted by SEC rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC-registered public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404, not being required to comply with the auditor requirements to communicate critical audit matters in the auditor's report on the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We have taken advantage of reduced reporting burdens in this Annual Report. In particular, in this Annual Report, we have provided only two years of audited financial statements and we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not "emerging growth companies."

We are also classified as a "smaller reporting company" and are exempt from certain disclosure requirements, which could make our stock less attractive to potential investors.

Rule 12b-2 of the Exchange Act defines a "smaller reporting company" as an issuer that is not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent that is not a smaller reporting company and that:

- Had a public float of less than $250 million as of the last business day of its most recently completed fiscal quarter, computed by multiplying the aggregate number of worldwide number of shares of its voting and non-voting common equity held by non-affiliates by the price at which the common equity was last sold, or the average of the bid and asked prices of common equity, in the principal market for the common equity; or
- In the case of an initial registration statement under the Securities Act or the Exchange Act for shares of its common equity, had a public float of less than $250 million as of a date within 30 days of the date of the filing of the registration statement, computed by multiplying the aggregate worldwide number of such shares held by non-affiliates before the registration plus, in the case of a Securities Act registration statement, the number of such shares included in the registration statement by the estimated offering price of the shares; or
- In the case of an issuer who had annual revenue of less than $100 million during the most recently completed fiscal year for which audit financial statements are available, had a public float as calculated under paragraph (1) or (2) of this definition that was either zero or less than $700 million.

As a "smaller reporting company" we are not required and may not include a Compensation Discussion and Analysis section in our proxy statements; we provide only three years of business development information; provide fewer years of selected data; and have other "scaled" disclosure requirements that are less comprehensive than issuers that are not "smaller reporting companies" which could make our stock less attractive to potential investors, which could make it more difficult for you to sell your shares.

As a "smaller reporting company," we may at some time in the future choose to exempt our Company from certain corporate governance requirements that could have an adverse effect on our public shareholders.

Under NYSE American rules, a "smaller reporting company," as defined in Rule 12b-2 under the Exchange Act, is not subject to certain corporate governance requirements otherwise applicable to companies listed on NYSE American. For example, a smaller reporting company is exempt from the requirement of having a compensation committee composed solely of directors meeting certain enhanced independence standards, as long as the compensation committee has at least two members who do meet such standards. Although we have determined not to avail ourselves of this or other exemptions from NYSE American requirements that are or may be afforded to smaller reporting companies while we will seek to maintain our shares on NYSE American, in the future we may elect to rely on any or all of these exemptions. By electing to utilize any such exemptions, our Company may be subject to greater risks of poor corporate governance, poorer management decision-making processes, and reduced results of operations from problems in our corporate organization. Consequently, if we were to avail ourselves of these exemptions, our stock price might suffer, and there is no assurance that we would be able to continue to meet all continued listing requirements of NYSE American from which we would not be exempt, including minimum stock price requirements.

Changes in funding for or disruption at the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations could hinder their ability to hire and retain key leadership and other personnel, delay the review and approval of regulatory submissions, limit the development or implementation of regulatory programs, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business

Federal agencies in the United States, including the FDA and the SEC, operate pursuant to annual appropriations and other political and budgetary processes, and may from time to time be subject to continuing resolutions, funding lapses, or other fiscal constraints. Without appropriation of sufficient funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years and may continue to fluctuate as a results of these factor as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. For example, the Trump administration has issued executive orders seeking to greatly reduce the size of the federal workforce, including through layoffs and severance packages offered to employees of federal agencies within the executive branch and independent agencies, including the FDA. Any such reduction in personnel may result in longer review times by the FDA and other agencies.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, most recently in October 1, 2025 through November 12, 2025, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs again, or if global health concerns or shortages in resources prevent the FDA or other regulatory authorities from conducting their regulatory inspections, reviews or other regulatory activities, including formal or informal interactions with product developers, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations or delay the review or effectiveness of required regulatory or securities filings.

The U.S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

With the start of the Trump Administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Recent and potential future changes to U.S. and non-U.S. tax laws could materially adversely affect our Company.

Existing, new, or future changes in tax laws, regulations, and treaties, or the interpretation thereof, in addition to tax policy initiatives and reforms under consideration in the United States or internationally and other initiatives could have an adverse effect on the taxation of international businesses. Furthermore, countries where we are subject to taxes, including the United States, are independently evaluating their tax policy and we may see significant changes in legislation and regulations concerning taxation.

Recently enacted U.S. tax legislation has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate, limiting interest deductions, and revising the rules governing NOLs. Many of these changes are effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, or the IRS, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities.

The reduction of the corporate tax rate under the legislation may cause a reduction in the economic benefit of deferred tax assets available to us.

As of December 31, 2025, we had federal and state net operating loss, or NOLs, carryforwards of approximately $9.9 million. Under the Tax Cuts and Jobs Act of 2017, or the Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, our NOLs generated in tax years beginning after December 31, 2020 may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020, is limited to 80% of taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act.

In addition, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership (some of which may be outside our control). As a result, our ability to use our pre-change NOLs and tax credits to offset post-change taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. 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.

We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our effective tax rates in the future in countries where we have operations and have an adverse effect on our overall tax rate in the future, along with increasing the complexity, burden, and cost of tax compliance. While some of the changes made by the tax legislation may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going-forward basis. We intend to work with our tax advisors and auditors to determine the full impact that the recent tax legislation as a whole will have on us.

We urge our stockholders to consult with their legal and tax advisors with respect to any such legislative changes and the potential tax consequences of investing in or holding our common stock.

Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters may materially impact reporting of our financial condition and results of operations.

Accounting principles generally accepted in the United States and related accounting pronouncements, implementation guidelines, and interpretations we apply to a wide range of matters that are relevant to our business, such as accounting for long-lived asset impairment and share-based compensation, are complex and involve subjective assumptions, estimates and judgments by our management. Changes in these rules or their interpretation or changes in underlying assumptions, estimates or judgments by our management could significantly change or add significant volatility to our reported or expected financial performance.

A potential failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, financial condition, and results of operations.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. generally accepted accounting principles, or GAAP. Under standards established by the Public Company Accounting Oversight Board, or PCAOB, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. The PCAOB defines a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented, or detected and corrected, on a timely basis.

We will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, regarding the effectiveness of our internal control over financial reporting starting with the second annual report filed by the Company after completion of our IPO and in each year thereafter. Our auditors, however, will not be required to attest to the effectiveness of our internal control over financial reporting until we are no longer deemed an Emerging Growth Company, which will not be until after we have been a public reporting company for five fiscal years or until we have annual gross revenues of more than $1.235 billion, whichever occurs sooner. If we are unable to assert that our internal control over financial reporting is effective, or when required in the future, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be adversely affected, and we could become subject to litigation or investigations by the stock exchange on which our common stock are listed, the SEC or other regulatory authorities, which could require additional financial and management resources and could have a material adverse effect on our business, financial condition, and results of operations.

The lack of public company experience of our management team could adversely impact our ability to comply with the reporting requirements of U.S. securities laws, which could have a materially adverse effect on our business.

Our officers have limited public company experience, which could impair our ability to comply with legal and regulatory requirements such as those imposed by Sarbanes-Oxley Act. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. Any such deficiencies, weaknesses or lack of compliance could have a materially adverse effect on our ability to comply with the reporting requirements of the Exchange Act, which is necessary to maintain our public company status. If we were to fail to fulfill those obligations, our ability to continue as a U.S. public company would be in jeopardy in which event you could lose your entire investment in our Company.

We could be subject to securities class action litigation.

In the past, when the market price of a stock has been volatile, holders of that stock sometimes have instituted securities class action litigation against the company that issued the stock following a decline in the market price of their securities. This risk is especially relevant for us because biotechnology companies have experienced significant share price volatility in recent years. Securities litigation against us, regardless of the merits or outcome, could result in substantial costs and divert the time and attention of our management from our business, which could have a material adverse effect on our business, financial condition, and results of operations.

Our directors' liability to us and stockholders is limited; claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our certificate of incorporation and bylaws provide that we will indemnify our directors and officers, in each case, to the fullest extent permitted by Delaware law. Pursuant to our bylaws and the DGCL, our directors will not be liable to the Company or any stockholders for damages for any breach of fiduciary duty, except (i) acts that breach his or her duty of loyalty to the Company or its stockholders; (ii) acts or omissions without good faith or involving intentional misconduct or knowing violation of the law; (iii) pursuant to Section 174 of the DGCL regarding director liability for unlawful payment of a dividend or unlawful stock purchase or redemption; or (iv) for any transaction from which the director derived an improper personal benefit. Accordingly, we will have a much more limited right of action against our directors that otherwise would be the case. This provision does not affect the liability of any director under federal or applicable state securities laws. In addition, we have entered into indemnification agreements with each of our executive officers and directors. The indemnification agreements provide the executive officers and directors with contractual rights to indemnification, expense advancement and reimbursement, to the fullest extent permitted under the DGCL. The bylaws also require us, if so requested, to advance expenses that such director or officer incurred in defending or investigating a threatened or pending action, suit or proceeding, provided that such person will return any such advance if it is ultimately determined that such person is not entitled to indemnification by us. Any claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Indemnity provisions in various agreements potentially expose us to substantial liability for intellectual property infringement, data protection, and other losses.

Our agreements with third parties may include indemnification provisions under which we agree to indemnify them for losses suffered or incurred as a result of claims of intellectual property infringement or other liabilities relating to or arising from our contractual obligations. Large indemnity payments could harm our business and financial condition. Although we normally contractually limit our liability with respect to such obligations, we may still incur substantial liability. Any dispute with a third party with respect to such obligations could have adverse effects on our relationship with that third party and relationships with other existing or new partners, harming our business.

The capital markets may experience periods of disruption, instability and economic uncertainty. Such market conditions may materially and adversely affect the debt and equity capital markets, which may have a negative impact on our business and operations.

From time to time, capital markets may experience periods of disruption, instability and economic uncertainty. Such periods may result in, among other things, write-offs, the re-pricing of credit risk, the failure of financial institutions or worsening general economic conditions, any of which could materially and adversely impact the broader financial and credit markets and reduce the availability of debt and equity capital for the market as a whole and, as a result, negatively affect our ability to access capital. Global financial markets have experienced heightened volatility in recent years. In addition, social and political tensions in the U.S. and around the world may contribute to increased market volatility, may have long-term effects on the U.S. and worldwide financial markets, and may cause economic uncertainties or deterioration in the U.S. and worldwide. There can be no assurance these market conditions will not occur or worsen in the future, including economic and political events in or affecting the world's major economies, such as the ongoing war between Russia and Ukraine and continued conflicts and political unrest in the Middle East and South America. Sanctions imposed by the U.S. and other countries in connection with hostilities between Russia and Ukraine, the war in Iran, conflicts in the Middle East, and the tensions between China and Taiwan have caused additional financial market volatility and affected the global economy. Concerns over future inflation volatility, economic recession, as well as interest rate volatility and fluctuations in oil and gas prices resulting from global production and demand levels, as well as geopolitical tension, have exacerbated market volatility. In addition, social unrest, changes regarding immigration and work permit policies and other political and security concerns may not abate, which may cause the debt and equity capital markets and our business to be adversely affected both within and outside of regions experiencing ongoing conflicts. Market uncertainty and volatility have also been magnified as a result of uncertainties regarding actual and potential shifts in U.S. and foreign trade, economic and other policies, including with respect to treaties and tariffs.

Further, volatility in the capital markets may make it difficult to raise equity capital or obtain debt financing, the results of which could cause a material adverse effect on our business, financial condition and/or results of operations. If we are unable to raise additional capital, we will not be able to fund our ongoing clinical trials and further develop our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein. We conduct risk assessments at least annually to identify cybersecurity threats. These risk assessments include identifying reasonably foreseeable potential internal and external risks, the likelihood of occurrence and any potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, controls and other safeguards we have put in place to manage such risks. Our risk management process also encompasses cybersecurity risks associated with the use of our major third-party vendors and service providers. For additional information regarding whether any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected or are reasonably likely to materially affect our company, including our business strategy, results of operations, or financial condition, please refer to Item 1A "Risk Factors" in this Annual Report on Form 10-K , including the risk factors entitled *"Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs," and "Our proprietary information, or that of our customers, suppliers and business partners, may be lost or we may suffer security breaches."*

Governance

One of the key functions of our Board of Directors is informed oversight of our risk management process, including risks arising from cybersecurity threats. Our Board of Directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our Chief Financial Officer is primarily responsible for assessing and managing material risks from cybersecurity threats on a day to day basis.

ITEM 2. PROPERTIES

Our corporate address is 2355 Westwood Blvd. #139, Los Angeles, CA, 90064. This is the address of our registered agent. We currently do not lease any properties, but if required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms. As of the date of this Annual Report, all of our operations are conducted virtually.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in material legal proceedings or be subject to claims arising in the ordinary course of our business. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources, and other factors, and there can be no assurances that favorable outcomes will be obtained. We are not presently party to any legal proceedings material to our operations or of which any of our property is the subject, nor are we aware of any such proceedings that are contemplated by a government authority.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on the NYSE American LLC, or NYSE American, under the symbol "KAPA."

Holders

As of March 31, 2026, we had 48 holders of record of our common stock and 21,411,198 shares of common stock issued and outstanding. This number of holders of record does not represent the actual number of beneficial owners of our common shares because shares are frequently held in "street name" by securities dealers and others for the benefit of individual owners who have the right to vote their shares.

Dividends

We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws, 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. In addition, our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

Securities authorized for issuance under equity compensation plans.

The following table provides information about the Company's common stock that may be issued under the Company's 2023 Equity Incentive Plan as of December 31, 2025.

Plan Category	Number of securities to be issued upon exercise or vesting of outstanding options, warrants, rights and restricted stock units	Weighted-average exercised price of outstanding options, warrants, rights and restricted stock units	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in first column)
Equity compensation plans approved by stockholders	772,605	$ 1.05	877,395
Equity compensation plans not approved by security holders	-	-	-
Total	772,605	1.05	877,395

Recent Sales of Unregistered Securities

See below "Recent Developments - January 2025 PIPE Offering."

Issuer Purchases of Equity Securities

None.

ITEM 6. [Reserved.]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

(in thousands, except for share amounts and per share data)

The following discussion and analysis should be read in conjunction with our financial statements and related notes included elsewhere in this Annual Report. This discussion and analysis and other parts of this Annual Report contain forward-looking statements based upon current beliefs that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations and intentions. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth under "Item 1A Risk Factors" and elsewhere in this Annual Report. You should carefully read the "Item 1A Risk Factors" of this Annual Report to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see "Disclosure Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company advancing therapeutics for cancer patients that are designed to overcome key hurdles in immune suppression and drug resistance.

Our mission is to advance our portfolio of innovative therapeutics to reverse key mechanisms of therapeutic resistance and immune suppression and transform the way cancer is treated. We have leveraged molecular insights of the mechanisms of therapeutic resistance and immune suppression to develop a new class of novel drugs that are designed to target drug resistance and checkpoints of immune suppression. As of the date of this Quarterly Report, our product candidates have not been approved as safe or effective by the FDA or any other comparable foreign regulator.

Since inception, our operations have focused on organizing and staffing our Company, business planning, raising capital, acquiring and developing our technology, establishing our intellectual property portfolio, identifying potential product candidates, and undertaking preclinical and clinical studies and manufacturing. We do not have any products approved for sale and have not generated any revenue from product sales.

Since inception, we have incurred significant operating losses. Our net losses were $5,447 and $2,603 for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $14,262. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, as we advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory approval for our current and future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel, and operate as a public company.

We will not generate revenue from product sales unless and until we successfully complete our clinical trials and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization partnership, we will likely incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing, and distribution activities.

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 public or private equity offerings and debt financings and other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as and when needed could have a material adverse effect on our business, results of operations and financial condition. No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to the Company. Even if the Company is able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our stockholders, in case of equity financing.

Recent Developments

Equity Line of Credit Agreement (ELOC)

On November 12, 2024, we entered into an ELOC agreement (the "ELOC Agreement") with Helena Global Investment Opportunities I LTD ("Helena"), pursuant to which Helena agreed to purchase from the Company up to $30,000 of common stock (the "ELOC Shares"), which the Company may exercise at any time following effectiveness of a registration statement at a price equal to the 95% of the lowest trading price during the three days following the Company's notice to Helena to exercise the ELOC Agreement. The Company issued 670,641 shares of restricted common stock (the "Commitment Fee Shares") to Helena as a "Commitment Fee" for the ELOC Agreement. The ELOC Agreement became available for the Company's use following the filing and effectiveness of a resale registration statement registering the ELOC Shares for resale. Following effectiveness of the resale registration statement (the "Effective Date"), the Commitment Fee Shares were subject to a "true-up" pursuant to which, as the shares are valued at less than $900 on the Effective Date, additional shares were issued to Helena to bring the ELOC Shares to the full $900 value.

The ELOC Agreement will terminate upon the following events: (i) the first day of the month next following the 36-month anniversary of the date of the ELOC Agreement or (ii) the date on which Helena has purchased the full $30,000 of ELOC Shares. The ELOC Agreement may also be terminated by the Company after its commencement, at the Company's discretion, provided that there are no advance notices outstanding for which common stock has yet to be issued, and the Company has paid all amounts owed to Helena under the ELOC Agreement, including the Commitment Fee shares.

At the Company's annual meeting of shareholders on June 10, 2025, a majority of the Company's shareholders approved the issuance in excess of 19.99% of the Company's common stock at a price below market value, in accordance with the terms of the ELOC Agreement and in compliance with Rule 713 of the NYSE American LLC Company Guide.

During the year ended December 31, 2025, in connection with its ELOC agreement with Helena, the Company sold 3,510,000 shares of its common stock to Helena for net proceeds of $3,205. The shares were issued to Helena during the year ended December 31, 2025.

Boustead Securities LLC ("Boustead") and D. Boral Capital LLC ("D. Boral") acted as placement agents (the "Placement Agents") in the ELOC offering and, following each exercise, are entitled to cash compensation of 7%, 1% non-accountable fees and warrants equal to 7%. To date, the Placement Agents have received total cash compensation equal to $313,225 and a total of 245,750 warrants to purchase common stock, exercisable at exercise prices of $0.40, $0.46 and $1.2308 per share, which warrants will expire five years from the date of grant.

January 2025 PIPE Offering

On January 14, 2025, the Company entered into a securities purchase agreement (the "Purchase Agreement") and registration rights agreement (the "Registration Rights Agreement") with the investor name therein (the "Investor") for the sale and issuance of 2,500,000 units (the "Pre-Funded Units"), with each Pre-Funded Unit consisting of a pre-funded warrant (the "Pre-Funded Warrant") to purchase one share of common stock, exercisable for $0.001 per share, and a common warrant (the "Common Warrant") to purchase one and one half shares of common stock, exercisable at $1.40 per share (the "January 2025 PIPE Offering").

On January 16, 2025, the Company closed the January 2025 PIPE Offering for a total purchase price of $3,498 (or $1.399 per Pre-Funded Unit), with an additional $2 payable upon the Investor's exercise of the Pre-Funded Warrants in full.

In advance of closing, on January 16, 2025, the Company and the Investor entered into an amended and restated Purchase Agreement (the "A&R Purchase Agreement"), which amended the terms of the Purchase Agreement to include a requirement that the Company obtain shareholder approval prior to issuing in excess of 19.99% of the Company's common stock and also amended the Common Warrants to make them immediately exercisable and reduce the exercise period from 5.5 years to five years. Other terms of the Purchase Agreement and Common Warrants remained the same.

Boustead and D. Boral acted as co-placement agents for the January 2025 PIPE Offering. In conjunction therewith, on January 16, 2025, the Company entered into a Placement Agent Agreement with Boustead (the "Placement Agent Agreement"). Under the terms of the Placement Agent Agreement, at closing, the Company paid the Placement Agents (i) a cash commission equal to 8% of the gross proceeds (including a 1% non-accountable expense fee) and (ii) warrants to purchase a total of 175,000 shares of common stock, exercisable at $1.40 per share, with the total cash and warrant compensation split equally between the Placement Agents.

On January 20, 2025, the Company obtained the approval of 55.4% of the shareholders (the "Majority Shareholders") for the issuance in excess of 19.99% of the Company's common stock at a price below market value, in compliance with Rule 713 of the NYSE American LLC Company Guide. On February 10, 2025, the Company filed the definitive Schedule 14C and the shareholder approval became effective on March 1, 2025.

2026 At the Market Offering.

On January 12, 2026, we entered into an at-the-market ("ATM") offering agreement (the "ATM Agreement") with H.C. Wainwright Co., LLC (the "Placement Agent") for the sale, from time to time, of up to $4,524,949 shares of our common stock. We registered the common stock offered under the ATM pursuant to prospectus supplement filed in conjunction with our shelf registration statement on Form S-3 (SEC File No. 333-292686), which was declared effective on January 23, 2026. Pursuant to the ATM Agreement, the Placement Agent is entitled to a placement agent fee of 3.0% of the gross sale price of shares sold under the ATM.

Components of Results of Operations

Net Sales

We have not generated any sales to date. No revenue was recorded from any sources during the years ended December 31, 2025 and 2024.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development Expenses

Dr. Ramachandran Murali is our Vice President of Research and Development. Dr. Murali is a doctor and scientist at Cedars-Sinai Medical Center, and is the inventor, with others, of three of the patented technologies that are subject to the Kairos-Cedars license agreements.

We are engaged in rolling out our Phase 1 and Phase 2 clinical trials for ENV 105 and a Phase 1 trial for KROS 201. In addition, we are continuously performing preclinical research including animal models of disease, medicinal chemistry laboratory studies, formulation, and toxicology and biodistribution studies. Our clinical development costs may vary significantly based on factors such as: per patient trial costs; the number of trials required for approval; the number of sites included in the trials; the location where the trials are conducted; the length of time required to enroll eligible patients; the number of patients that participate in the trials; the number of doses that patients receive; the drop-out or discontinuation rates of patients; potential additional safety monitoring requested by regulatory agencies; the duration of patient participation in the trials and follow-up; the cost and timing of manufacturing our product candidates; the phase of development of our product candidates; and the efficacy and safety profile of our product candidates.

The successful development and commercialization of product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including the following: the timing and progress of nonclinical and clinical development activities; the number and scope of nonclinical and clinical programs we decide to pursue; raising necessary additional funds; the progress of the development efforts of parties with whom we may enter into collaboration arrangements; our ability to maintain our current development program and to establish new ones; our ability to establish new licensing or collaboration arrangements; the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority; the receipt and related terms of regulatory approvals from applicable regulatory authorities; the availability of drug substance and drug product for use in production of our product candidate; establishing and maintaining agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if our product candidates are approved; our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally; our ability to protect our rights in our intellectual property portfolio; the commercialization of our product candidates, if and when approved; obtaining and maintaining third-party insurance coverage and adequate reimbursement; the acceptance of our product candidate, if approved, by patients, the medical community and third-party payors; competition with other products; the impact of any business interruptions to our operations, including the timing and enrollment of patients in our planned clinical trials, or to those of our manufacturers, suppliers, or other vendors resulting from any pandemic or public health crisis; and a continued acceptable safety profile of our therapies following approval.

A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, corporate and business development, as well as administrative functions. General and administrative expenses also include legal fees relating to patent, corporate, IPO-related matters, and SEC reporting matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative travel expenses; marketing expenses and other operating costs.

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

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Revenues	$ -	$ -
Operating expenses:		
Research and development	2,135	414
General and administrative	3,437	1,929
Total operating expenses	5,572	2,343
Loss from operations	(5,572)	(2,343)
Other income (expenses):		
Interest expense	-	(35)
Financing costs	-	(670)
Debt discount amortization	-	(154)
Gain on settlement of accounts payable	-	599
Interest income	125	-
Total other income (expenses)	125	(260)
Net loss	$ (5,447)	$ (2,603)

Research and Development Expenses

The table below summarizes our research and development expenses for the years ended December 31, 2025 and 2024:

Research and Development Expenses:	December 31, 2025	December 31, 2024
Clinical trial and related expenses	$ 2,135	$ 414
Total research and development expenses	$ 2,135	$ 414

Research and development expenses were $2,135 and $414 for the years ended December 31, 2025 and 2024, respectively. The increase in R&D expenses in 2025 primarily related to our Phase 2 trial in prostate cancer beginning in 2024.

General and Administrative Expenses

The table below summarizes our general and administrative expenses for the years ended December 31, 2025 and 2024:

General and Administrative Expenses:	December 31, 2025	December 31, 2024
Stock-related expenses	$ 341	$ 219
Officer and board compensation and wages	566	481
Patent related expenses	75	134
Legal expenses	202	149
Accounting expenses	206	181
Other professional service expenses and fees	510	242
Fees relating to license agreements	-	138
Insurance expenses	385	151
Vendor advances amortization expense	871	-
Intangible amortization expense	160	160
Other expenses	121	74
Total general and administrative expenses	$ 3,437	$ 1,929

General and administrative expenses were $3,437 and $1,929 for the years ended December 31, 2025 and 2024, respectively. Significant changes between periods consisted of the increase in other professional service expenses and fees, primarily related to being a publicly traded company; the increase in insurance expenses, primarily D&O; and the increase in vendor advance amortization expense in 2025, relating to our vendor advances in 2025.

Other Income (Expenses)

Other income (expenses) was $125 and $(260) for the years ended December 31, 2025 and 2024, respectively. In 2025, other income was interest income earned from our money market account. In 2024, other expenses were interest expense of $35, financing costs of $670 and debt discount amortization of $154, with other income relating to a gain on the settlement of accounts payable of $599.

Liquidity and Capital Resources

The Company has experienced recurring losses from operations since inception and incurred a net loss of $5,447 and used cash in operations of $3,441 during the year ended December 31, 2025. These factors raise substantial doubt about the Company's ability to continue as a going concern. The ability of the Company to continue as a going concern is dependent upon the Company's ability to raise additional funds and implement its strategies. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

As of December 31, 2025, the Company had cash and short-term investments of $4,491. Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings and debt financings, or other capital sources such as potential collaborations, strategic alliances, licensing arrangements and other arrangements. Based on our research and development plans, we expect that our existing cash balance may not enable us to fund our planned operating expenses and capital expenditure requirements for at least the next 12 months from the date of filing of this Annual Report. 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. In addition, because the design and outcome of our anticipated and any future clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current products or any future product candidates. Additionally, although we have the ability to raise funds through our S-1 and S-3 registration statements filed in 2025 and 2026, we may not receive some or all of these available proceeds, due to certain factors. The failure to receive all or some of the proceeds would exhaust our available capital resources sooner than expected and will require us to obtain further funding to achieve our business objectives.

No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to the Company. Even if the Company is able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our shareholders, in the event of an equity financing.

Cash Flows

The table below summarizes our cash flow activities for the years ended December 31, 2025 and 2024:

Net cash provided by (used in):	December 31, 2025	December 31, 2024
Operating activities	$ (3,441)	$ (3,955)
Investing activities	-	-
Financing activities	6,660	5,134
Net increase in cash and cash equivalents	$ 3,219	$ 1,179

Operating Activities

During the year ended December 31, 2025, we used cash from operating activities of $3,441, compared to $3,955 used during the year ended December 31, 2024. During the year ended December 31, 2025, we incurred a net loss of $5,447 and had non-cash expenses of $2,182, compared to a net loss of $2,603 and non-cash expenses of $632 during the year ended December 31, 2024. The primary non-cash expense in 2025 was the amortization of vendor advances of $2,170.

The net change in operating assets and liabilities during the year ended December 31, 2025 used cash of $806, compared to $1,984 used during the year ended December 31, 2024. The primary use of cash relating to operating assets and liabilities during the year ended December 31, 2025, was the decrease in accounts payable and accrued expenses. The primary use of cash during the years ended December 31, 2024, was the increase in vendor advances.

Financing Activities

During the year ended December 31, 2025, we provided cash from financing activities of $6,660, compared to $5,134 provided during the year ended December 31, 2024. For the year ended December 31, 2025, cash provided by financing activities consisted of proceeds from our private financing of $3,058 and proceeds of $3,602 from our ELOC. Net cash provided in 2024 was from net proceeds from our IPO of $5,524 and proceeds from notes payable – officers of $142. Net cash used in 2024 consisted of the payment of deferred offering costs of $390 and the repayment of notes payable – officers of $142.

Debt Agreements

Conversion of Amounts Due to Related Parties

During the year ended December 31, 2021, shareholders of the Company, and a company whose principal stockholder is also a stockholder of the Company, advanced the Company $14. The advances accrued no interest, were unsecured and were due on demand. During the year ended December 31, 2022, the Company repaid $10 of the advances, and as of December 31, 2023 and September 17, 2024 (the date of the closing of the Company's IPO), a total of $4 was outstanding. During the three months ended September 30, 2024, the officers agreed to automatically convert the principal into shares of the Company's common stock upon the closing of the IPO transaction. Upon the closing of the IPO, all of the principal automatically converted into 1,664 shares of the Company's common stock based on the conversion price of $2.40, which was 60% of the IPO closing price of $4.00. As of December 31, 2024, no principal or interest was due on the advances.

Notes Payable to Officers

During the year ended December 31, 2024, the Company entered into note payable agreements with three of its officers in the aggregate total of $142. The notes accrued interest at 7.5% per annum, were unsecured and were due one year from the date of issuance. During the year ended December 31, 2024, the principal of $142 and accrued interest of $3 were repaid in the form of stock. In connection with the loans, the Company issued the officers 36,270 shares of the Company's common stock. No amounts were owed to the officers as of December 31, 2024.

Convertible Notes Payable

During the year ended December 31, 2022, the Company entered into several convertible note payable agreements with certain investors totaling $675. The notes accrue interest at 6% per annum, are unsecured and are due by April 2025. If the Company does not close an IPO transaction within 12 months of the date of the note, the Company would have the choice of paying off the principal plus all accrued and unpaid interest, or the note's principal balance would increase to 110% of its original balance. The notes are convertible at the option of the noteholders into shares of the Company's common stock at a price per share as defined in the agreement or will automatically be converted into shares of the Company's common stock at 60% of the IPO price per share upon the closing of an IPO transaction. The net proceeds to the Company relating to the convertible notes, was $564. As of December 31, 2022, $675 of principal was outstanding on the notes, in addition to $17 of accrued and unpaid interest.

During the year ended December 31, 2023, no principal or interest payments were made on the notes and the notes accrued interest of $43. As the Company did not close its IPO transaction within 12 months of the date of the notes, the notes' principal balance increased to 110% of their original balance, or an increase of $68. As of December 31, 2023, $743 of principal was outstanding on the notes and $60 of accrued and unpaid interest.

During the year ended December 31, 2024, as the Company had not closed its IPO transaction within 12 months of the date of issuance of the notes, a portion of the notes' principal balance increased to 110% of their previous balance, or an increase of $49. As of September 17, 2024, $792 of principal was outstanding on the notes and $92 of accrued and unpaid interest.

Upon closing of the Company's IPO on September 17, 2024, the principal amount of $792, plus the accrued and unpaid interest of $92, totaling $884, automatically converted into 368,371 shares of the Company's common stock based on the principal and accrued interest due as of September 17, 2024. No principal or interest was owed on the notes as of December 31, 2024.

Conversion of Accounts Payable

During the year ended December 31, 2024, the Company entered into an agreement with Cedars-Sinai Medical Center ("Cedars") under which Cedars agreed to convert $750 of the total accounts payable due to them into 312,500 shares of the Company's common stock, with such conversion to occur upon the closing of the Company's IPO. The conversion price of the shares was equal to 60% of the per share IPO price, or $2.40 per share. Upon the closing of the IPO, the shares were issued to Cedars and the debt was converted.

Also, during the year ended December 31, 2024, the Company entered into another agreement with Cedars under which Cedars agreed to convert $200 of the total accounts payable due to them into 150,830 shares of the Company's common stock. The conversion price of the shares was equal to 60% of the closing price of the Company's common stock on the date of the agreement, or $1.33 per share.

During the year ended December 31, 2024, the Company entered into an agreement with its Chief Financial Officer, under which the Chief Financial Officer agreed to convert $172 of the total accounts payable due to him into 51,610 shares of the Company's common stock with such conversion to occur upon the closing of the Company's IPO. The conversion price of the shares was equal to 83% of the IPO price. Upon the closing of the IPO, the shares were issued to our Chief Financial Officer. No amounts were owed to the Chief Financial Officer as of December 31, 2024.

Contractual Obligations and Commitments

Kairos Agreement with Prevail Infoworks, Inc.

In August 2024, the Company entered into a master service and technology agreement with Prevail Infoworks, Inc. ("Prevail"), pursuant to which Prevail agreed to provide certain clinical research services to the Company. As part of the agreement, the Company must make an advance payment of $900 to Prevail before they begin their services and, at such time as we notify Prevail to engage their services related to the relevant clinical trial, or six months from the date of the agreement, pay approximately $80 per month during the time Prevail performs clinical research services for the Company's Phase 2 ENV 105 prostate and Phase 1 ENV 105 lung clinical trials. The agreement with Prevail is subject to cancellation at any time upon 30 days' written notice to the other party. The Company made the advance payment to Prevail in October 2024.

Kairos Agreement with PreCheck Health Services, Inc.

On September 20, 2024, the Company entered into a bioassay services agreement (the "Bioassay Services Agreement") with PreCheck Health Services, Inc., a Florida-based corporation ("PreCheck"). Pursuant to the Bioassay Services Agreement, PreCheck will provide certain biomarker screening services for the Company's ongoing carotuximab (ENV105) clinical trials in order to assist the Company in identifying lung and prostate cancer patients suitable to the Company's ongoing Phase 1 clinical trials for lung cancer patients and Phase 2 trials for patients with castrate resistant prostate cancer. In order to identify biomarkers for patient screening and therapy monitoring using carotuximab (ENV105), PreCheck will utilize its SolidTumorCheck+ platform for the somatic gene expression analysis of biopsy tissue samples derived from patients with lung and prostate cancer, as part of the Company's ongoing clinical trials. In furtherance of these efforts, PreCheck will develop a companion diagnostic to support its identification of such patients with a three gene PCR analysis or other genetic analysis, which diagnostic test will then be developed and submitted to the FDA for castrate-resistant prostate cancer patients and for lung cancer patients on Tagrisso. In exchange for PreCheck's services, and according to the terms of the Bioassay Services Agreement, the Company paid $900 to PreCheck as an advance for the future laboratory services to be performed. The term of the agreement is one year from the effective date.

Kairos Agreement with CEO.CA Technologies Ltd.

On September 23, 2024, the Company entered into an advisory and consulting services agreement (the "CEO.CA Agreement") with CEO.CA Technologies Ltd., a Canadian company ("CEO.CA"), pursuant to which CEO.CA will provide certain internet-based financial information and communications services for a period of one year for a services fee of $250. The service fee is an advance on future services to be performed. The CEO.CA Agreement includes such services as strategic news placement, news releases, interviews, monthly analytics and a video launch. The CEO.CA Agreement contains other customary clauses, including representations and warranties, indemnification clauses and governing law clauses.

Kairos Agreement with Belair Capital Advisors Inc.

On September 23, 2024, the Company entered into a strategic advisory agreement (the "Strategic Advisory Agreement") with Belair Capital Advisors Inc. ("BCA"). BCA, a venture capital and corporate finance advisory firm, has been a long-term investor and advisor to the Company and frequently works with early-stage pharmaceutical companies. The strategic advisory services consist of corporate strategy, market positioning and long-term growth plans within the pharmaceutical sector, digital marketing and engagement, market research analysis and business development assistance, among other things. During the one-year term of the Strategic Advisory Agreement, in exchange for its services, the Company will pay BCA $365 fee and will issue BCA 50,000 RSUs, which will vest at the end of six months.

Kairos Agreement with Cross Current Capital LLC

On October 1, 2024, the Company entered into a consulting agreement (the "Consulting Agreement") with Cross Current Capital LLC, a limited liability company organized under the laws of Puerto Rico ("Cross Current"), and Alan Masley (the "Advisor"), pursuant to which Cross Current agreed to provide certain financial and business consulting services to the Company including, but not limited, to (a) help drafting a public company competitive overview, (b) help preparing and/or reviewing a valuation analysis, (c) help in drafting marketing materials and presentations, (d) reviewing the Company's business requirements and discuss financing and businesses opportunities, (e) investor marketing, (f) investor relations introductions, (g) legal counsel introductions, (h) auditor introductions, (i) investment banking and research introductions, (j) M&A canvassing and ways to grow the business organically, and (k) stand by capital markets advisory services. For the services rendered thereunder, the Company agreed to pay Cross Current $200,000 in cash and agreed to issue to the Advisor restricted shares of the Company's common stock, issuable under the Company's 2023 Equity Inventive Plan, in an amount equal to $500,000 (the "Shares"), which Shares will vest at the end of six months after issuance. Should the Shares be valued at less than $500 on the date of vesting, the Shares will be subject to a "true-up" pursuant to which additional shares will be issued to the holder to bring the value of to $500 as of that date (the "True-up Shares") and the True-up Shares will be deemed fully vested as of the date of issuance. The term of the Consulting Agreement is 24 months and can be extended for another 12 months upon the written consent of both parties. The Company made the $200 payment in October 2024.

Exclusive License Agreements with Cedars

We have entered into four Exclusive License Agreements with Cedars which grants us licensing rights with respect to certain patent rights owned by Cedars as follows:

1. Methods of use of compounds that bind to RelA of NFkB;

2. Composition and methods for treating fibrosis;

3. Compositions and methods for treating cancer and autoimmune diseases; and

4. Method of generating activated T cells for cancer therapy.

On June 2, 2021, our wholly owned subsidiary, Enviro, entered into two Exclusive License Agreements with Cedars, which granted Enviro exclusive licensing rights (which include the right to sublicense) with respect to certain patent rights owned by Cedars, as follows:

- an Exclusive License Agreement (the "Enviro-Cedars License Agreement (Mitochondrial DNA)") for Enviro to develop, manufacture, use and sell products utilized or derived from patent rights worldwide related to the "Compositions and Methods for Treating Diseases and Conditions by Depletion of Mitochondrial DNA from Circulation and for Detection of Mitochondrial DNA" invented by Dr. Neil Bhowmick and others; and

- an Exclusive License Agreement, (the "Enviro-Cedars License Agreement (Endoglin Antagonism)" and, collectively with the Enviro-Cedars License Agreement (Mitochondrial DNA), the "Enviro-Cedars License Agreements") for Enviro to develop, manufacture, use and sell products utilized or derived from the patent rights and technical information worldwide related to the "Sensitization of Tumors to Therapies Through Endoglin Antagonism" invented by Dr. Bhowmick and others.

Agreement with former Chief Financial Officer

We have an agreement with our former Chief Financial Officer that requires us to pay $50 upon the completion of raising more than $900 in a debt or an equity financing. $50 was owed as of December 31, 2024 and that amount was paid to the former CFO during the period ended March 31, 2025.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing research activities, particularly as we pursue the advancement of our product candidates through clinical trials. In addition, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend on numerous variables, including: the initiation, progress, timing, costs and results of the clinical trials for our product candidates or any future product candidates we may develop; the initiation, progress, timing, costs and results of nonclinical studies for our product candidates or any future product candidates we may develop; our ability to maintain our relationships with key collaborators; the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more nonclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to; the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights; the effect of competing technological and market developments; the costs of continuing to grow our business, including hiring key personnel and maintain or acquiring operating space; market acceptance of any approved product candidates, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors; the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies; the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing; the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize; and our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We expect that we will continue to require additional funding to complete the clinical development and commercialization of our product candidates, if we receive regulatory approval, and pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize ourselves.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect the rights of our current common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate 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.

Critical Accounting Policies and Significant Judgments and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the date of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with GAAP, we base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances at the time such estimates are made. Actual results may differ materially from our estimates and judgments under different assumptions or conditions. We periodically review our estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates are reflected in our financial statements prospectively from the date of the change in estimate.

We define our critical accounting policies as those accounting principles that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. While our significant accounting policies are more fully described in Note 2 to our unaudited financial statements appearing elsewhere in this Quarterly Report, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

Vendor Advances

We have entered into various contracts with service providers pursuant to which we pay the vendor an advance at the beginning of the contractual period. These vendor advances could be paid by us either in cash or in shares of common stock, depending on the terms of the contract. The advances are reduced by the accumulated value of the services performed by the vendor or are amortized on a straight-line basis over the service period, whichever is shorter. As of December 31, 2024, advances to vendors totaled $3,115, with $2,615 being paid in cash and $500 being paid with shares of our common stock. Amortization expense relating to the vendor advances during the year ended December 31, 2024 was $256, with an unamortized balance of $2,859 as of December 31, 2024. During the year ended December 31, 2025, an additional advance to a vendor totaled $156, with the advance being paid with shares of our common stock, and amortization expense relating to the vendor advances was $2,170, with an unamortized balance of $845 as of December 31, 2025.

Deferred Offering Costs

Agreement with Helena Global Investment Opportunities

On November 12, 2024, we entered into an agreement with Helena Global Investment Opportunities I LTD ("Helena") pursuant to which we will have the right to issue and sell to Helena, from time to time, and Helena shall purchase from us, up to $30,000 of the Company's shares of common stock (the "Equity Line of Credit"). The Equity Line of Credit became available to us after we filed a registration statement on Form S-1 registering the shares issuable under the Equity Line of Credit and such registration statement became effective. In exchange for the Equity Line of Credit, we are obligated to issue Helena a certain number of shares of common stock, calculated using $900 divided by the lowest one-day VWAP during the five trading days prior to entry into the agreement. As a result, we issued Helena 670,641 shares of its common stock valued at $1,377 on the date of issuance. We accounted for the value of the shares issued as deferred offering costs. The shares vested on the date of the agreement, were issued to Helena, and were subject to a "true up" based upon the value of the stock after we filed and obtained effectiveness of the registration statement registering the ELOC shares for resale. At December 31, 2024, the balance of the deferred offering costs was $1,377.

On April 24, 2025, we issued another 384,459 shares of its common stock to Helena. The fair value of the shares on the date of grant was $328. We recorded the fair value of the shares as deferred offering costs as of the same date. During the year ended December 31, 2025, we amortized $614 of these costs as shares were issued under the agreement. As of December 31, 2025, the balance of the deferred offering costs was $1,091.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred.

At the end of each reporting period, we compare payments made to third-party service providers to the estimated progress toward completion of the applicable research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that we estimate has been made as a result of the service provided, we may record net prepaid or accrued expenses relating to these costs. As of December 31, 2024 and 2025, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted based on the fair value of the award on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company has elected to recognize forfeitures as they occur. The reversal of compensation cost previously recognized for an award that is forfeited because of a failure to satisfy a service or performance condition is recognized in the period of the forfeiture. Generally, the Company issues stock options with only service-based vesting conditions and records the expense for these awards using the straight-line method over the requisite service period.

The Company classifies stock-based compensation expense in its statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The Company was a private company until the listing of the Company's common stock on the NYSE American on September 16, 2024 and the subsequent closing of its IPO on September 17, 2024. The Company estimates the fair value of its common stock using an appropriate valuation methodology, in accordance with the framework of the American Institute of Certified Public Accountants' Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, guideline public company information, the prices at which the Company sold its common stock to third parties in arms' length transactions, the rights and preferences of securities senior to the Company's common stock at the time, and the likelihood of achieving a liquidity event such as an initial public offering or sale. Significant changes to the assumptions used in the valuations could result in different fair values of stock options or warrants at each valuation date, as applicable.

The fair value of each stock option or warrant grant is estimated using the Black-Scholes option-pricing model. The Company was a private company and lacked company-specific historical and implied volatility information. Therefore, it estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies within the biotechnology industry with characteristics similar to the Company. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. 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. Expected dividend yield is zero, based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Commitments and Contingencies

From time to time, we may have certain contingent liabilities that arise in the ordinary course of business. We evaluate the likelihood of an unfavorable outcome in legal or regulatory proceedings to which we are a party and record a loss contingency on an undiscounted basis when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. These judgments are subjective and based on the status of such legal proceedings, the merits of our defenses, and consultation with legal counsel. Actual outcomes of these legal proceedings may differ materially from our estimates. We estimate accruals for legal expenses when incurred as of each balance sheet date based on the facts and circumstances known to us at that time.

Off-Balance Sheet Arrangements

During the years ended December 31, 2025 and 2024, we did not have, and we do not currently have, any off-balance sheet arrangements (as defined under SEC rules).

Recent Accounting Pronouncements

For a description of recently issued accounting standards that may have a material impact on our financial statements or will otherwise apply to our operations, please see Note 2 to our audited financial statements appearing elsewhere in this Annual Report.

Emerging Growth Company Status

As an "emerging growth company," the Jumpstart Our Business Startups Act of 2012 permits us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a "smaller reporting company," this item is not required.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Kairos Pharma, Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Kairos Pharma, Ltd. (the "Company") as of December 31, 2025, the related consolidated statements of operations, changes in shareholders' equity (deficit) and cash flows for the year ended December 31, 2025, 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 the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 audit. 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 audit 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Weinberg & Company P.A.
Weinberg & Company P.A.

We have served as the Company's auditor since 2025.
Los Angeles, CA
March 31, 2026

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of
Kairos Pharma, Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Kairos Pharma, Ltd. (the "Company") as of December 31, 2024, the related consolidated statements of operations, shareholders' equity and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audit, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit 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 audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor from 2021 through 2025 (such date takes into account the acquisition of the attest business of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

Los Angeles, CA
April 15, 2025

Kairos Pharma, Ltd.
Consolidated Balance Sheets
(In thousands, except for share amounts and par value data)

	December 31,	
	2025	**2024**
ASSETS		
Current Assets		
Cash and cash equivalents	$ 4,491	$ 1,272
Vendor advances, net	845	2,859
Prepaid expenses and other current assets	51	38
Total Current Assets	5,387	4,169
Deferred offering costs	1,091	1,377
Intangible assets, net	62	222
Total Other Assets	1,153	1,599
TOTAL ASSETS	$ 6,540	$ 5,768
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities		
Accounts payable and accrued expenses	$ 199	$ 992
Total Current Liabilities	199	992
Commitments and contingencies		
Shareholders' Equity		
Preferred stock, par value $0.001, 20,000,000 shares authorized; no shares issued and outstanding, respectively;	-	-
Common stock, par value $0.001, 100,000,000 shares authorized; 20,821,353 and 13,736,597 shares issued and outstanding, respectively;	21	14
Additional paid-in capital	20,582	13,577
Accumulated deficit	(14,262)	(8,815)
Total Shareholders' Equity	6,341	4,776
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 6,540	$ 5,768

The accompanying notes are an integral part of these consolidated financial statements.

Kairos Pharma, Ltd.
Consolidated Statements of Operations
(in thousands, except for share amounts and per share data)

	Years Ended December 31,	
	2025	**2024**
Revenues	$ -	$ -
Operating expenses:		
Research and development	2,135	414
General and administrative	3,437	1,929
Total operating expenses	5,572	2,343
Loss from operations	(5,572)	(2,343)
Other income (expenses):		
Interest expense	-	(35)
Debt discount amortization	-	(154)
Financing costs	-	(670)
Gain on settlement of accounts payable	-	599
Interest income	125	-
Total other income (expenses)	125	(260)
NET LOSS	$ (5,447)	$ (2,603)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.30)	$ (0.23)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING BASIC AND DILUTED	18,427,787	11,356,451

The accompanying notes are an integral part of these consolidated financial statements.

Kairos Pharma, Ltd.
Consolidated Statements of Shareholders' Equity (Deficit)
(in thousands, except share amounts)

	Common Stock		Additional	Accumulated	
	Shares	Amount	Paid-in Capital	Deficit	Total
Balance, December 31, 2023	10,562,640	$ 11	$ 4,123	$ (6,212)	$ (2,078)
Issuance of common shares upon the closing of the initial public offering, net of offering costs	1,550,000	2	4,650		4,652
Issuance of common shares upon conversion of convertible notes payable and accrued interest	368,371	-	884		884
Issuance of common shares upon conversion of accounts payable	514,940	-	1,789		1,789
Issuance of common shares upon conversion of amounts due to related parties	1,664	-	7		7
Issuance of common shares for deferred offering costs	670,641	1	1,877		1,878
Fair value of warrants issued in connection with convertible notes payable	-	-	29		29
Fair value of vested restricted stock units	68,341	-	218		218
Net loss for the year ended December 31, 2024	-	-	-	(2,603)	(2,603)
Balance, December 31, 2024	13,736,597	$ 14	$ 13,577	$ (8,815)	$ 4,776
Proceeds from the sale of common shares and pre-funded warrants, net of offering costs	2,500,000	2	3,056	-	3,058
Fair value of common shares issued for deferred offering costs	384,459	-	327	-	327
Common shares issued for cash through equity line of credit, net of expenses	3,510,000	4	2,984	-	2,988
Issuance of common shares recorded as a vendor advance	534,188	1	156	-	157
Fair value of vested restricted stock units	144,707	-	482	-	482
Issuance of common shares through cashless exercise of stock warrants	11,402	-	-	-	-
Net loss for the year ended December 31, 2025	-	-	-	(5,447)	(5,447)
Balance, December 31, 2025	20,821,353	$ 21	$ 20,582	$ (14,262)	$ 6,341

The accompanying notes are an integral part of these consolidated financial statements.

Kairos Pharma, Ltd.
Consolidated Statements of Cash Flows
(In thousands)

	Years Ended December 31,	
	2025	**2024**
Cash Flows from Operating Activities		
Net loss	$ (5,447)	$ (2,603)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of intangible asset	160	160
Amortization of vendor advances	2,170	-
Amortization of debt discount	-	154
Fair value of vested restricted stock units	482	218
Fair value of common shares issued in connection with the conversion of accounts payable	-	670
Fair value of warrants issued in connection with convertible notes payable	-	29
Gain on settlement of accounts payable	-	(599)
Changes in operating assets and liabilities:		
Vendor advances	-	(2,358)
Prepaid expenses and other current assets	(13)	(30)
Accounts payable and accrued expenses	(793)	404
Net cash used in operating activities	(3,441)	(3,955)
Cash Flows from Financing Activities		
Proceeds from the sale and exercise of prefunded warrants	3,058	-
Proceeds from the equity line of credit	3,602	-
Proceeds from common stock issued for cash in connection with the closing of the initial public offering	-	5,524
Proceeds from notes payable - officers	-	142
Repayment of notes payable - officers		(142)
Payment of deferred offering costs	-	(390)
Net cash provided by financing activities	6,660	5,134
Net increase in cash and cash equivalents	3,219	1,179
Cash and cash equivalents, beginning of period	1,272	93
Cash and cash equivalents, end of period	$ 4,491	$ 1,272
Supplemental cash flows disclosures:		
Interest paid	$ -	$ 3
Taxes paid	$ -	$ -
Supplemental non-cash financing disclosures:		
Common shares issued for deferred offering costs	$ 327	$ 1,377
Common shares issued for vendor advances	$ 157	$ 500
Reclassification of deferred offering costs to shareholders' equity	$ 614	$ 872
Conversion of convertible notes payable and accrued interest to shareholders' equity	$ -	$ 884
Conversion of accounts payable to shareholders' equity	$ -	$ 1,348
Conversion of amounts due to related parties to shareholders' equity	$ -	$ 4
Issuance of convertible notes payable recorded as debt discount	$ -	$ 49

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1 – BASIS OF PRESENTATION

Organization and Operations

Kairos Pharma, Ltd. (the "Company" or "Kairos") was incorporated on June 17, 2013 under the laws of the state of California as NanoGB13, Inc. The Company changed its name to Kairos Pharma, Ltd. on July 15, 2016 and subsequently converted into a Delaware corporation under the same name, Kairos Pharma, Ltd., on May 10, 2023. The Company is an early-stage biotechnology company focused on the development of immunotherapy and cell therapy treatments for oncology.

Liquidity and Capital Resources

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As reflected in the accompanying consolidated financial statements, the Company has experienced recurring losses from operations since inception and incurred a net loss of $5,447 and used cash in operations of $3,441 during the year ended December 31, 2025. These factors raise substantial doubt about the Company's ability to continue as a going concern. The ability of the Company to continue as a going concern is dependent upon the Company's ability to raise additional funds and implement its strategies. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

As of December 31, 2025, the Company had cash and short-term investments of $4,491. Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings and debt financings, or other capital sources such as potential collaborations, strategic alliances, licensing arrangements and other arrangements. Based on our research and development plans, we expect that our existing cash balance may not enable us to fund our planned operating expenses and capital expenditure requirements for at least the next 12 months from the date of filing of this Annual Report. 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. In addition, because the design and outcome of our anticipated and any future clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our current products or any future product candidates. Additionally, although we have the ability to raise funds through our Form S-1 and S-3 registration statements filed in 2025 and 2026, we may not receive some or all of these available proceeds, due to certain factors. The failure to receive all or some of the proceeds would exhaust our available capital resources sooner than expected and will require us to obtain further funding to achieve our business objectives.

No assurance can be given that any future financing will be available or, if available, that it will be on terms that are satisfactory to the Company. Even if the Company is able to obtain additional financing, it may contain undue restrictions on our operations, in the case of debt financing, or cause substantial dilution for our shareholders, in the event of an equity financing.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Consolidation

The accompanying consolidated financial statements and accompanying notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The accompanying consolidated financial statements include the accounts of the Company and its former wholly-owned subsidiary, Enviro Therapeutics, Inc. ("Enviro") which was dissolved in October 2025. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the financial statement date and reported amounts of revenue and expenses during the reporting period. Significant estimates are used in the valuation of accruals for potential liabilities, amortization of vendor advances and deferred offering costs, valuations of stock-based compensation, the realization of deferred tax assets, and impairment analysis and useful life for intangible assets among others. Actual results could differ from these estimates.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash deposits. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. The Company has not experienced any losses on deposits since its inception.

Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less on the date of purchase to be cash equivalents. The Company's cash equivalents consisted of $4,326 in money market funds as of December 31, 2025. There were no cash equivalents as of December 31, 2024. The underlying securities in the money market funds held by the Company are all government backed securities.

Intangible Assets

The Company's intangible assets are stated at fair value as of the date acquired, less accumulated amortization. Amortization is calculated based on the estimated useful lives of the assets, which were determined to be five years, using the straight-line method. The intangible asset consists of a licensing agreement that the Company acquired through its acquisition of Enviro during the year ended December 31, 2021, with an acquisition cost of $800. Amortization expense relating to the intangible asset during the years ended December 31, 2025 and 2024 was $160, with an unamortized balance of $62 and $222 at December 31, 2025 and 2024, respectively.

Impairment of Long-Lived Assets

The Company applies the provisions of ASC Topic 360, *Property, Plant, and Equipment*, which addresses financial accounting and reporting for the impairment of long-lived assets. A long-lived asset that is held and used should be tested for recoverability whenever events or changes in circumstances indicate that the carrying amount of the asset group may not be recoverable. If the estimated undiscounted future cash flows are less than the carrying value, an impairment determination is required. In that event, a loss is recognized based on the amount by which the carrying amount exceeds the fair value of the long-lived assets. No impairment was recorded relating to the Company's intangible asset during the years ended December 31, 2025 and 2024.

Income (Loss) Per Share

Basic loss per share is computed by dividing net loss applicable to common stockholders by the weighted average number of outstanding common shares during the period. Shares of restricted stock are included in the basic weighted average number of common shares outstanding from the time they vest. Diluted loss per share is computed by dividing the net loss applicable to common stockholders by the weighted average number of common shares outstanding plus the number of additional common shares that would have been outstanding if all dilutive potential common shares had been issued.

For the years ended December 31, 2025 and 2024, the basic and diluted shares outstanding were the same, as potentially dilutive shares were considered anti-dilutive. The potentially dilutive securities consisted of the following:

	December 31, 2025	December 31, 2024
Warrants to purchase common stock	4,281,038	278,188
Restricted stock units	772,605	172,000
Total	5,053,643	450,188

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity issuances as deferred offering costs until such equity issuances are consummated. After consummation of the equity issuance, these costs are recorded as a reduction in the capitalized amount associated with the equity issuance. Should the equity issuance be delayed or abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the Company's statement of operations. As of December 31, 2024, the Company incurred $1,377 of deferred offering costs related to the Company's pending equity line of credit ("ELOC") offering. During the year ended December 31, 2025, the Company issued common shares with a fair value of $328 related to the ELOC. The Company's registration statement registering the ELOC was declared effective on April 24, 2025, and the Company will amortize these costs as cost of capital as funds are raised, based upon the Company's estimate of the ultimate funds raised under the ELOC. During the year ended December 31, 2025, $614 of deferred offering costs were amortized as cost of capital, and as of December 31, 2025, total deferred offering costs were $1,091 related to the ELOC.

Fair Value Measurements

The Company determines the fair value of its assets and liabilities based on the exchange price in U.S. dollars that would be received to sell 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 maximize the use of observable inputs and minimize the use of unobservable inputs. The Company uses a fair value hierarchy with three levels of inputs, of which the first two are considered observable and the last unobservable, to measure fair value:

- *Level 1* — Quoted prices in active markets for identical assets or liabilities.
- *Level 2* — Inputs, other than Level 1, that are observable, either directly or indirectly, 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 and that are significant to the fair value of the assets or liabilities.

The carrying amounts of financial instruments such as cash, and accounts payable and accrued liabilities, approximate the related fair values due to the short-term maturities of these instruments.

Cash equivalents consisted of money market funds at December 31, 2025. Money market funds were valued by the Company using quoted prices in active markets for identical securities, which represent a Level 1 measurement within the fair value hierarchy.

Income Taxes

Income tax expense is based on pretax financial accounting income. Deferred tax assets and liabilities are recognized for the expected tax consequences of temporary differences between the tax bases of assets and liabilities and their reported amounts. Valuation allowances are recorded to reduce deferred tax assets to the amount that will more likely than not be realized. The Company recorded a 100% valuation allowance against its deferred tax assets as of December 31, 2025 and 2024.

The Company accounts for uncertainty in income taxes using a two-step approach to recognize and measure uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50 percent likely of being realized upon settlement. The Company classifies the liability for unrecognized tax benefits as current to the extent that the Company anticipates payment (or receipt) of cash within one year. Interest and penalties related to uncertain tax positions are recognized in the provision for income taxes.

Patents and Patent Application Costs

Although the Company believes that its patents and underlying technology have continuing value, the amount of future benefits to be derived from the patents is uncertain. Patent costs are therefore expensed as incurred and are included in general and administrative expenses on the accompanying consolidated Statements of Operations. Patent expenses were $79 and $134 during the years ended December 31, 2025 and 2024.

Research and Development Costs

The Company expenses its research and development costs as incurred. Research and developments costs for the years ended December 31, 2025 and 2024 were $2,135 and $414, respectively.

Research Contract Costs and Accruals

The Company has entered into various research and development-related contracts with companies inside the United States. These agreements are generally cancellable, and related costs are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant 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.

Stock-Based Compensation

The Company measures all stock options, certain warrants and other stock-based awards granted based on the fair value of the award on the date of the grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company has elected to recognize forfeitures as they occur. The reversal of compensation cost previously recognized for an award that is forfeited because of a failure to satisfy a service or performance condition is recognized in the period of the forfeiture. Generally, the Company issues stock options with only service-based vesting conditions and records the expense for these awards using the straight-line method over the requisite service period.

The Company classifies stock-based compensation expense in its statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The Company was a private company until the completion of its IPO on September 17, 2024. Prior to the IPO, the Company estimated the fair value of common stock using an appropriate valuation methodology, in accordance with the framework of the American Institute of Certified Public Accountants' Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, guideline public company information, the prices at which the Company sold its common stock to third parties in arms' length transactions, the rights and preferences of securities senior to the Company's common stock at the time, and the likelihood of achieving a liquidity event such as an initial public offering or sale. Significant changes to the assumptions used in the valuations could result in different fair values of stock options or warrants at each valuation date, as applicable. Subsequent to September 17, 2024, the Company estimates the fair value of common stock based on its historical trading price at the date of grants.

The fair value of each stock option or warrant grant is estimated using the Black-Scholes option-pricing model. Until the completion of its IPO, the Company was a private company and lacked company-specific historical and implied volatility information. Therefore, it estimated its expected stock volatility based on the historical volatility of a publicly traded set of peer companies within the biotechnology industry with characteristics similar to the Company. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options or warrants. The expected term of stock options or warrants granted to non-employees is equal to the contractual term of the option award. 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. Expected dividend yield is zero, based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

Warrant Instruments

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the instruments' specific terms and applicable authoritative guidance in ASC 480 and ASC 815. The assessment considers whether the instruments are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the instruments meet all of the requirements for equity classification under ASC 815, including whether the instruments are indexed to the Company's own common stock and whether the instrument holders could potentially require net cash settlement in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and, for liability-classified warrants, at each reporting period end date while the warrants are outstanding.

Marketing and Advertising Costs

Marketing and advertising expenses were not material for the years ended December 31, 2025 and 2024.

Recent Accounting Pronouncements

In November 2024, FASB issued ASU 2024-03 Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40) Disaggregation of Income Statement Expenses. The guidance in ASU 2024-03 requires public business entities to disclose in the notes to the financial statements, among other things, specific information about certain costs and expenses including purchases of inventory; employee compensation; and depreciation and amortization expense for each caption on the income statement where such expenses are included. The update is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted, and the amendments may be applied prospectively to reporting periods after the effective date or retrospectively to all periods presented in the financial statements. We are currently evaluating the provisions of this guidance and assessing the potential impact on our financial statement disclosures.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statements.

NOTE 3 – VENDOR AGREEMENTS

Vendor Advances

The Company has entered into various contracts with service providers pursuant to which the Company pays the vendor an advance at the beginning of the contractual period. These vendor advances could be paid by the Company either in cash or in shares of common stock, depending on the terms of the contract. The advances are reduced by the accumulated value of the services performed by the vendor or are amortized on a straight-line basis over the service period, whichever is shorter. As of December 31, 2024, advances to vendors totaled $3,115, with $2,615 being paid in cash and $500 being paid with shares of the Company's common stock. Amortization expense relating to the vendor advances during the year ended December 31, 2024 was $256, with an unamortized balance of $2,859 as of December 31, 2024. During the year ended December 31, 2025, an additional advance to a vendor totaled $156, with the advance being paid with shares of the Company's common stock, and amortization expense relating to the vendor advances was $2,170, with an unamortized balance of $845 as of December 31, 2025.

Vendor advances consisted of the following at December 31, 2025, and 2024:

	December 31, 2025	December 31, 2024
Prevail Infoworks (a)	$ 900	$ 900
PreCheck Health Services (b)	900	900
CEO.CA Technologies (c)	250	250
Belair Capital Advisors (d)	365	365
Cross Current Capital (e)	856	700
	3,271	3,115
Less: accumulated amortization	(2,426)	(256)
Vendor advances, net	$ 845	$ 2,859

The remaining unamortized balance of $845 as of December 31, 2025, will be fully amortized during the year ending December 31, 2026.

(a) Kairos Agreement with Prevail Infoworks, Inc.

On August 1, 2024, the Company entered into a master service and technology agreement with Prevail Infoworks, Inc. ("Prevail"), pursuant to which Prevail agreed to provide certain clinical research services to the Company. As part of the agreement, the Company was required to make an advance payment of $900 to Prevail before commencement of services and, at such time as we notify Prevail to engage their services related to the relevant clinical trial, or six months from the date of the agreement, pay approximately $80 per month during the time Prevail performs clinical research services for the Company's Phase 2 ENV 105 prostate and Phase 1 ENV 105 lung clinical trials. The agreement with Prevail is subject to cancellation at any time upon 30 days' written notice to the other party. The Company made the advance payment to Prevail in October 2024 and it is included in vendor advances on the accompanying Balance Sheet as of December 31, 2025 and 2024. The unamortized balance of the advance was $500 as of December 31, 2025.

(b) Kairos Agreement with PreCheck Health Services, Inc.

On September 20, 2024, the Company entered into a bioassay services agreement (the "Bioassay Services Agreement") with PreCheck Health Services, Inc., a Florida-based corporation ("PreCheck"). Pursuant to the Bioassay Services Agreement, PreCheck will provide certain biomarker screening services for the Company's ongoing carotuximab (ENV105) clinical trials in order to assist the Company in identifying lung and prostate cancer patients suitable to the Company's ongoing Phase 1 clinical trials for lung cancer patients and Phase 2 clinical trials for patients with castrate resistant prostate cancer. In exchange for PreCheck's services, and according to the terms of the Bioassay Services Agreement, the Company paid $900 to PreCheck as an advance for the future laboratory services to be performed. The payment of $900 is included in vendor advances on the accompanying Balance Sheet as of December 31, 2025 and 2024. The term of the agreement is one year from the effective date. The advance was fully amortized as of December 31, 2025.

(c) Kairos Agreement with CEO.CA Technologies Ltd.

On September 23, 2024, the Company entered into an advisory and consulting services agreement (the "CEO.CA Agreement") with CEO.CA Technologies Ltd., a Canadian company ("CEO.CA"), pursuant to which CEO.CA will provide certain internet-based financial information and communications services for a period of one year for a services fee of $250. The service fee is an advance on future services to be performed. The CEO.CA Agreement includes services such as strategic news placement, news releases, interviews, monthly analytics and a video launch. The CEO.CA Agreement contains other customary clauses, including representations and warranties, indemnification clauses and governing law clauses. The payment of $250 is included in vendor advances on the accompanying Balance Sheet as of December 31, 2025 and 2024. The advance was fully amortized as of December 31, 2025.

(d) Kairos Agreement with Belair Capital Advisors Inc.

On September 23, 2024, the Company entered into a strategic advisory agreement (the "Strategic Advisory Agreement") with Belair Capital Advisors Inc. ("BCA"). BCA, a venture capital and corporate finance advisory firm, has been a long-term investor and advisor to the Company and frequently works with early-stage pharmaceutical companies. The strategic advisory services provided by BCA consist of corporate strategy, market positioning and long-term growth plans within the pharmaceutical sector, digital marketing and engagement, market research analysis and business development assistance, among other things. During the one-year term of the Strategic Advisory Agreement, in exchange for its services, the Company will pay BCA a $365 fee and will issue BCA 50,000 RSUs, which will vest at the end of six months following the date of issuance. The payment of $365 is included in vendor advances on the accompanying Balance Sheet as of December 31, 2025 and 2024. The advance was fully amortized as of December 31, 2025.

(e) Kairos Agreement with Cross Current Capital LLC

On October 1, 2024, the Company entered into a consulting agreement (the "Consulting Agreement") with Cross Current Capital LLC, a limited liability company organized under the laws of Puerto Rico ("Cross Current"), and Alan Masley (the "Advisor"), pursuant to which Cross Current agreed to provide certain financial and business consulting services to the Company including, but not limited, to (a) help drafting a public company competitive overview, (b) help preparing and/or reviewing a valuation analysis, (c) help in drafting marketing materials and presentations, (d) reviewing the Company's business requirements and discuss financing and businesses opportunities, (e) investor marketing, (f) investor relations introductions, (g) legal counsel introductions, (h) auditor introductions, (i) investment banking and research introductions, (j) M&A canvassing and ways to grow the business organically, and (k) stand by capital markets advisory services. For the services rendered thereunder, the Company agreed to pay Cross Current $200 in cash and agreed to issue to the Advisor $500 of restricted shares of the Company's common stock under the Company's 2023 Plan, which was calculated at 367,647 shares (the "Shares") as of the date of the agreement and were issuable at December 31, 2024. The term of the Consulting Agreement is 24 months and can be extended for another 12 months upon the written consent of both parties. The Company made the $200 payment in October 2024. The payment of $200 and the value of the shares issued of $500 are included in vendor advances on the accompanying Balance Sheet as of December 31, 2025 and 2024.

The 367,647 shares issuable in 2024 were subject to a "true up" on April 1, 2025, at which time additional shares were either issuable to the Advisor or to be returned by the Advisor to the Company in order to ensure the shares were valued at $500 as of April 1, 2025. Accordingly, on April 1, 2025, the Company issued an additional 166,541 shares of its common stock to the Advisor to bring the value to $500. All the issuable shares were issued during the year ended December 31, 2025. The fair value of the additional shares on the date of grant was $156. The Company recorded the fair value of the shares as a vendor advance as of the same date. The unamortized balance of the advance was $345 at December 31, 2025.

NOTE 4 – DEFERRED OFFERING COSTS

Agreement with Helena Global Investment Opportunities

On November 12, 2024, the Company entered into an agreement with Helena Global Investment Opportunities I LTD ("Helena") pursuant to which the Company will have the right to issue and sell to Helena, from time to time, and Helena shall purchase from the Company, up to $30,000 of the Company's shares of common stock (the "Equity Line of Credit"). The Equity Line of Credit became available to the Company after the Company filed a registration statement on Form S-1 registering the shares issuable under the Equity Line of Credit and such registration statement became effective. In exchange for the Equity Line of Credit, the Company is obligated to issue Helena a certain number of shares of common stock, calculated using $900 divided by the lowest one-day VWAP during the five trading days prior to entry into the agreement. As a result, the Company issued Helena 670,641 shares of its common stock valued at $1,377 on the date of issuance. The Company accounted for the value of the shares issued as deferred offering costs. The shares vested on the date of the agreement, were issued to Helena, and were subject to a "true up" based upon the value of the stock after the company filed and obtained effectiveness of the registration statement registering the ELOC shares for resale. At December 31, 2024, the balance of the deferred offering costs was $1,377.

On April 24, 2025, the Company issued another 384,459 shares of its common stock to Helena. The fair value of the shares on the date of grant was $328. The Company recorded the fair value of the shares as deferred offering costs as of the same date. During the year ended December 31, 2025, the Company amortized $614 of these costs as shares were issued under the agreement. As of December 31, 2025, the balance of the deferred offering costs was $1,091.

NOTE 5 – SHAREHOLDERS' EQUITY

Common Stock

Authorized Shares

The Company's Certificate of Incorporation, as filed with the State of Delaware on May 10, 2023, following the Company's conversion from a California corporation into a Delaware corporation, authorizes the Company to issue up to 120,000,000 shares, consisting of 100,000,000 shares of common stock, par value of $0.001 per share, and 20,000,000 shares of preferred stock, par value $0.001 per share. Holders of shares of common stock have full voting rights, one vote for each share held of record. Shareholders are entitled to receive dividends as may be declared by the board of directors out of funds legally available and share pro rata in any distributions with shareholders upon liquidation. Shareholders have no conversion, pre-emptive or subscription rights. All outstanding shares of common stock are fully paid and non-assessable. As of December 31, 2025 and 2024, there were 20,821,353 and 13,736,597 shares of common stock issued and outstanding, respectively, and no shares of preferred stock outstanding, respectively.

Common Stock Issued for Cash Upon Closing of the Company's IPO

On September 17, 2024, the Company completed the IPO of its common stock in which the Company issued and sold 1,550,000 shares of its common stock at a public offering price of $4.00 per share. The total gross proceeds of the IPO were $6,200 and the Company raised $5,524 in net proceeds after deducting underwriting discounts and commissions and offering expenses payable by the Company, excluding deferred offering costs of $872. The underwriters were granted a 45-day option to purchase up to an additional 232,500 shares of common stock from the Company. No additional shares were sold under the 45-day option.

On September 17, 2024, pursuant to the underwriting agreement, the Company issued common stock purchase warrants to the underwriters to purchase up to 108,500 shares of the Company's common stock, at an exercise price of $4.80 per share, subject to adjustments. The warrants will be exercisable during the period commencing on March 16, 2025 and ending on September 17, 2029, and may be exercised on a cashless basis under certain circumstances.

Common Stock Issued Upon Conversion of Convertible Notes Payable and Accrued Interest

During the year ended December 31, 2022, the Company entered into several convertible note payable agreements with certain investors totaling $675, with adjustments increasing the principal balance to $792 as of September 17, 2024, the date of the Company's IPO. Upon closing of the Company's IPO, the principal amount of $792, plus the accrued and unpaid interest of $92, totaling $884, automatically converted into 368,371 shares of the Company's common stock based on the principal and accrued interest due as of September 17, 2024.

Common Stock Issued Upon Conversion of Accounts Payable

During the year ended December 31, 2024, the Company entered into an agreement with Cedars-Sinai Medical Center ("Cedars") under which Cedars agreed to convert $750 of the total accounts payable due to them into 312,500 shares of the Company's common stock, with such conversion to occur upon the closing of the Company's IPO. The conversion price of the shares was equal to 60% of the per share IPO price, or $2.40 per share. Upon the closing of the IPO, the shares were issued to Cedars and the debt was forgiven. The fair value of the shares was $1,250. The Company recorded the difference between the fair value of the shares and the debt forgiven as a financing cost of $500, which was recorded during the year ended December 31, 2024.

Also, during the year ended December 31, 2024, the Company entered into another agreement with Cedars under which Cedars agreed to convert $200 of the total accounts payable due to them into 150,830 shares of the Company's common stock. The conversion price of the shares was equal to 60% of the closing price of the Company's common stock on the date of the agreement, or $1.33 per share. The fair value of the shares was $333. The Company recorded the difference between the fair value of the shares and the debt forgiven as a financing cost of $133, which was recorded during the year ended December 31, 2024.

During the year ended December 31, 2024, the Company entered into an agreement with its Chief Financial Officer ("CFO"), under which he agreed to convert $172 of the total accounts payable due to him into 51,610 shares of the Company's common stock with such conversion to occur upon the closing of the Company's IPO. The conversion price of the shares was equal to 83% of the IPO price. Upon the closing of the IPO, the shares were issued to the CFO. The fair value of the shares was $206. The Company recorded the difference between the fair value of the shares and the accounts payable forgiven as a financing cost of $34, which was recorded during the year ended December 31, 2024. No amounts were owed to the CFO as of December 31, 2024.

In summary, during the year ended December 31, 2024, the company issued 514,940 shares of its common stock with a fair value of $1,789 relating to the conversion of its account payable.

Common Stock Issued Upon Conversion of Amounts Due to Related Parties

During the year ended December 31, 2021, shareholders of the Company, and a company whose principal stockholder is also a stockholder of the Company, advanced the Company $14. As of September 17, 2024, the date of the closing of the Company's IPO, a total of $4 was outstanding.

During the year ended December 31, 2024, the officers agreed to automatically convert the principal into shares of the Company's common stock upon the closing of the IPO transaction. Upon the closing of the IPO, all of the principal automatically converted into 1,664 shares of the Company's common stock based on the conversion price of $2.40, which was 60% of the IPO closing price of $4. As the officers received 666 additional shares based on the 40% discounted price, the fair value of those shares, $3, was recorded as a financing cost during the year ended December 31, 2024. As of December 31, 2024, no principal or interest was due on the advances.

Common Stock Issued for Advances to Vendors

On October 1, 2024, the Company entered into a consulting agreement (the "Consulting Agreement") with Cross Current Capital LLC, a limited liability company organized under the laws of Puerto Rico ("Cross Current"), and Alan Masley (the "Advisor"), pursuant to which Cross Current agreed to provide certain financial and business consulting services to the Company. For the services rendered thereunder, the Company agreed to issue to the Advisor $500 of restricted shares of the Company's common stock under the Company's 2023 Plan, which was calculated at 367,647 shares (the "Shares") as of the date of the agreement. The Shares were subsequently issued to Cross Current in 2025. The value of the shares issued of $500 are included in Vendor Advances on the accompanying Balance Sheet as of December 31, 2025 and 2024 (see Note 3).

The Shares were subject to a "true up" on April 1, 2025, at which time additional shares were either issuable to the Advisor or to be returned by the Advisor to the Company in order to ensure the shares were valued at $500 as of April 1, 2025. Accordingly, on April 1, 2025, the Company issued an additional 166,541 shares of its common stock to the Advisor to bring the value to $500. The fair value of the additional shares on the date of grant was $157. The Company recorded the fair value of the shares as a Vendor Advance as of the same date (see Note 3).

Common Stock Issued for Cash Upon Closing of the Company's Private Financing

On January 14, 2025, the Company entered into a securities purchase agreement ("SPA") and registration rights agreement with an investor for the sale and issuance of 2,500,000 units (the "Pre-Funded Units"), with each Pre-Funded Unit consisting of a pre-funded warrant to purchase one share of common stock, exercisable for $0.001 per share, and a common warrant to purchase one and one half shares of common stock (an aggregate of 3,750,000), exercisable at $1.399 per share. On January 16, 2025, the Company closed on the sale of the Pre-Funded Units for a total purchase price of $3,500 (or $1.40 per Pre-Funded Unit). Net proceeds received by the Company relating to the financing, and subsequent exercise of prefunded warrants was $3,058.

The pre-funded warrants have an exercise price of $0.001 per share and are immediately exercisable and will expire when exercised in full. The common warrants have an exercise price of $1.40 per share, will be exercisable six months from issuance and will expire five and a half years from the issuance date. During the year ended December 31, 2025, the investor exercised 2,500,000 shares of the pre-funded warrants and as of December 31, 2025, there were no pre-funded shares remaining unexercised.

Common Stock Issued for Cash Upon Exercise of the Company's Equity Line of Credit (ELOC)

During the year ended December 31, 2025, in connection with its ELOC agreement with Helena, the Company sold 3,510,000 shares of its common stock to Helena for net proceeds of $2,988, which includes the allocation of deferred offering costs of $614. The shares were issued to Helena during the year ended December 31, 2025.

Adoption of the 2023 Equity Incentive Plan

In July 2023, the Company's board of directors and stockholders adopted the 2023 Equity Incentive Plan (the "2023 Plan"). Under the 2023 Plan, the Company may grant incentive stock options to employees, including employees of any parent or subsidiary, and nonstatutory stock options, stock appreciation rights, restricted stock awards, RSU awards, performance awards and other forms of stock compensation to employees, directors and consultants, including employees and consultants of the Company's affiliates. As approved, a total of 1,650,000 shares of common stock were initially reserved for issuance under the 2023 Plan. As of December 31, 2025, and 2024, a total of 877,395 shares and 1,478,000 remained available for issuance under the 2023 Plan, respectively.

Grant of Restricted Stock Units (RSUs)

The following table summarizes restricted common stock activity during the years ended December 31, 2024 and 2025:

	Number of Restricted Shares	Fair Value	Weighted Average Grant Date Fair Value
Unvested, December 31, 2023	—	$ —	$ —
Granted	240,341	532	2.21
Vested	(68,341)	(218)	3.19
Forfeited	—	—	—
Unvested, December 31, 2024	172,000	314	1.83
Granted	745,312	981	1.32
Vested	(144,707)	(482)	3.33
Forfeited	—	—	—
Unvested, December 31, 2025	772,605	$ 813	$ 1.05

On October 8, 2025, the Company's Compensation Committee of the board of directors approved the grant of an aggregate total of 667,940 RSUs to the Company's executive officers and directors for their services to be performed from October 2025 to October 2026. The RSUs were granted under the Company's 2023 Equity Incentive Plan and were valued at $875 on the date of grant. Additionally, the Company's independent directors received an aggregate total of 57,252 RSUs, with a value of $75 on the date of grant. Each RSU represents the right to receive one share of the Company's common stock upon vesting. The RSUs will vest in full on October 8, 2026, the first anniversary following the grant date, subject to the recipient's continuous service with the Company through such vesting date. Notwithstanding the foregoing vesting schedule, in the event of a change in control of the Company (as defined in the Plan) occurring prior to the vesting date, all unvested RSUs will become fully vested immediately upon the occurrence of such change in control.

On September 23, 2024, the Company entered into a strategic advisory agreement with Belair Capital Advisors Inc. ("Belair"). During the one-year term of the agreement, in exchange for its services, the Company issued Belair 50,000 RSUs, which vest nine months from the date of issuance. The fair value of the shares on the date of grant was $100, which value will be amortized over the one-year service period of the agreement. None of these shares vested or were issued during the year ended December 31, 2024. During the years ended December 31, 2025, the 50,000 RSUs vested and the shares were issued to Belair. As of December 31, 2025, no RSUs remained unvested.

Upon the closing of the Company's IPO, the Company entered into agreements with each of its four officers. Such agreements provided for annual grants of RSUs in accordance with the terms of the Company's 2023 Equity Incentive Plan. The RSUs vest over one- or two-year periods and are subject to full acceleration of vesting upon the sale of the Company. Upon the closing of the Company's IPO in September 2024, the Company granted the officers 92,000 RSUs. The fair value of the shares on the date of grant was $226. None of these RSUs vested during the year ended December 31, 2024. During the years ended December 31, 2025, a total of 78,000 RSUs vested, and the shares were issued to the officers. As of December 31, 2025, 14,000 RSUs remained unvested.

Upon the closing of the Company's IPO, the Company entered into agreements with each of its three independent directors. The Company's policy provides that, upon initial election or appointment to its board of directors, each new non-employee director will be granted a one-time grant, or Director Initial Grant, that will vest in substantially equal annual installments over a period of three years. The Director Initial Grant is subject to full acceleration of vesting upon the sale of the Company, in accordance with the terms of the Company's 2023 Plan. In 2024, a total of 30,000 RSUs were granted to the directors. The fair value of the RSUs on the date of grant was $43. None of the RSUs vested during the year ended December 31, 2024. During the years ended December 31, 2025, an additional 20,120 RSUs were granted to the Company's new director with a fair value of $31. During the year ended December 31, 2025, a total of 16,707 shares vested, and 33,413 RSUs remained unvested.

During the years ended December 31, 2025, the Company recorded $482 of stock compensation-related expense for the fair value vesting of restricted common stock. As of December 31, 2025, $813 of unamortized compensation remained.

Stock Warrants

The table below summarizes the Company's warrant activities for years ended December 31, 2024 and 2025:

	Number of Warrant Shares	Exercise Price Range Per Share	Weighted Average Exercise Price
Balance, December 31, 2023	150,000	$ 4.17	$ 4.17
Granted	128,188	2.40 – 4.80	4.43
Cancelled	—	—	—
Exercised	—	—	—
Forfeited/Expired	—	—	—
Balance, December 31, 2024	278,188	2.40 - 4.80	4.29
Granted	6,670,700	0.001 – 1.40	0.87
Cancelled	—	—	—
Exercised	(2,517,850)	0.001 – 0.46	0.004
Forfeited/Expired	(150,000)	4.17	4.17
Balance, December 31, 2025	4,281,038	$ 0.40 – 4.80	$ 1.48
Vested and exercisable, December 31, 2025	4,281,038	$ 0.40 – 4.80	$ 1.48

The following table summarizes information concerning outstanding and exercisable warrants as of December 31, 2025:

	Warrants Outstanding			Warrants Exercisable		
Range of Exercise Prices	Number Outstanding	Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$ 0.40 - 0.46	17,850	4.42	$ 0.46	17,850	4.42	$ 0.46
1.23 - 2.40	4,154,688	4.02	1.40	4,154,688	4.02	1.40
4.80	108,500	3.75	4.80	108,500	3.75	4.80
$ 0.40 - 4.80	4,281,038	4.01	$ 1.48	4,281,038	4.01	$ 1.48

Warrant Grants

On January 14, 2025, as amended on January 16, 2025, the Company entered into a securities purchase agreement ("SPA") and registration rights agreement with a select investor. In connection with the agreement, on January 16, 2025, the Company issued the investor a pre-funded warrant to purchase up to 2,500,000 shares of the Company's common stock at an exercise price of $0.001 per share. The warrant is immediately exercisable and will expire when exercised in full. During the years ended December 31, 2025, the SPA investor exercised 2,500,000 shares of the pre-funded warrant, and as of December 31, 2025, there were no shares remaining unexercised. The investor also received a warrant to purchase up to 3,750,000 shares of the Company's common stock at an exercise price of $1.40 per share. The warrant will be exercisable six months from the date of issuance (July 2025) and will expire five years from the issuance date. All the warrant shares were exercisable as of December 31, 2025.

On January 16, 2025, the Company issued a warrant to purchase common stock to the underwriters of the SPA for the purchase of 175,000 shares of the Company's common stock at an exercise price of $1.40 per share. The warrant vested upon grant. The warrant was issued to the underwriters as they were the placement agents for the SPA noted above. The warrant expires five years from the date of grant.

In May and June 2025, the Company issued warrants to purchase common stock to the underwriters of the SPA for the purchase of 35,700 shares of the Company's common stock at exercise prices of $0.40 and $0.46 per share. The warrants vested upon grant. The warrants were issued to the underwriters as they were the placement agents for the SPA noted above. The warrants expire five years from the date of grant. During the year ended December 31, 2025, a total of 17,850 shares were exercised under a cashless exercise, leaving 17,850 shares outstanding and exercisable. A total of 11,402 shares of the Company's common stock were issued pursuant to cashless exercise.

In July 2025, the Company issued warrants to purchase common stock to the underwriters of the SPA for the purchase of 210,000 shares of the Company's common stock at an exercise price of $1.23 per share. The warrants vested upon grant. The warrants were issued to the underwriters as they acted as placement agents for the SPA noted above. The warrants expire five years from the date of grant.

On September 17, 2024, upon the closing of the IPO, the Company issued stock warrants to the participating underwriters for the purchase of up to 108,500 shares of the Company's common stock, at an exercise price of $4.80 per share, subject to adjustment. The warrants will be exercisable during the period commencing on March 16, 2025, and ending on September 16, 2029, and may be exercised on a cashless basis under certain circumstances.

On September 17, 2024, upon the closing of the IPO, the Company issued a stock warrant to the underwriters for the purchase of 19,688 shares of common stock at an exercise price of $2.40 per share. The warrant vested upon grant. The warrant was issued to the underwriters as they were the placement agents for the convertible notes payable (see Note 5). The Company valued the warrant using a Black-Scholes pricing model with the following weighted average assumptions: fair value of the Company's stock price of $2.46 per share, the expected term of 2.5 years, volatility of 100%, dividend rate of 0%, and risk-free interest rate of 3.49%. The fair value of the warrant of $29 was recorded to General and Administrative expense during the year ended December 31, 2024. The warrant expires five years from the date of grant.

The intrinsic value for warrant shares outstanding as of December 31, 2025 was $4.

NOTE 6 – COMMITMENTS AND CONTINGENCIES

Kairos Exclusive License Agreements with Cedars-Sinai Medical Center (Cedars)

The Company has entered into four Exclusive License Agreements with Cedars, each of which grants the Company licensing rights with respect to certain patent rights owned by Cedars as follows:

1. Methods of use of compounds that bind to RelA of NFkB;
2. Composition and methods for treating fibrosis;
3. Compositions and methods for treating cancer and autoimmune diseases; and
4. Method of generating activated T cells for cancer therapy.

For each of the exclusive license agreement in items 1, 2 and 3, the Company was required to pay an initial license fee of $5, reimburse Cedars for patent protection costs ranging from approximately $9 to $61, pay an annual maintenance fee of $10, and pay royalties based on 3.75% of net sales and pay other non-royalty sublicense fees ranging from 5% to 35% of sales of products. In addition, for items 1, 2 and 3, the Company is required to pay Cedars based on the following milestones:

- $150 upon the successful completing of Phase I clinical trial;
- $250 (for items 1 and 2) and $500 (for item 3) upon the successful completing of Phase II clinical trial for a product and receipt of Food and Drug Administration ("FDA") approval for a Phase III clinical trial;
- $1,500 upon receipt of FDA approval of a new drug application or equivalent foreign regulatory approval in a non-United States major commercial market; and
- $250 upon cumulative net sales exceeding $5,000.

For the exclusive license agreement in item 4, the Company is required to pay an initial license fee of $50 upon raising $500 in capital, pay an annual maintenance fee of $10, pay royalties based on 4.25% of patent product sales and 0.5% of other sales and pay other non-royalty sublicense fees ranging from 5% to 35%. In addition, the Company is required to pay Cedars based on the following milestones:

- $150 upon the successful completing of Phase I clinical trial;
- $250 upon the successful completing of Phase II clinical trial and receipt of Food and Drug Administration ("FDA") or equivalent regulatory agency in another jurisdiction approval for a Phase III clinical trial;
- $1,500 upon receipt of FDA approval of a new drug application; and
- $2,500 upon cumulative net sales exceeding $50,000.

As of December 31, 2025, no amounts were due under the Exclusive License Agreements between Cedars and the Company.

Enviro Therapeutics

On June 2, 2021, the Company's then-wholly owned subsidiary, Enviro, entered into two Exclusive License Agreements with Cedars, which granted Enviro exclusive licensing rights (which include the right to sublicense) with respect to certain patent rights owned by Cedars, as follows:

- an Exclusive License Agreement (the "Enviro-Cedars License Agreement (Mitochondrial DNA)") for Enviro to develop, manufacture, use and sell products utilized or derived from patent rights worldwide related to the "Compositions and Methods for Treating Diseases and Conditions by Depletion of Mitochondrial DNA from Circulation and for Detection of Mitochondrial DNA" invented by Dr. Neil Bhowmick and others; and
- an Exclusive License Agreement (the "Enviro-Cedars License Agreement (Endoglin Antagonism)" and, collectively with the Enviro-Cedars License Agreement (Mitochondrial DNA), the "Enviro-Cedars License Agreements") for Enviro to develop, manufacture, use and sell products utilized or derived from the patent rights and technical information worldwide related to the "Sensitization of Tumors to Therapies Through Endoglin Antagonism" invented by Dr. Neil Bhowmick and others.

In exchange for each of the licenses, pursuant to the terms of the Exclusive License Agreements, Enviro was required to pay an upfront license fee in the mid four-figures and low-five figures, respectively. Enviro was also required to reimburse Cedars for the costs in the mid-to-high six figures incurred in the prosecution of the patent rights subject to the Enviro-Cedars License Agreements prior to the date of execution of such agreements, and certain costs and fees then outstanding aggregating in the low-six figures owed by Kairos pursuant to the Kairos-Cedars License Agreements. Pursuant to the Enviro-Cedars License Agreements, Cedars was also to receive royalty payments of a mid-single-digit percentage of net sales of products associated with the licensed patent right and less than one percent of net sales of other products derived from Cedars' technical information, with a minimum annual royalty fee in the low five-digits due beginning on the third anniversary of the effective date of the Enviro-Cedars License Agreements. To the extent Enviro derived non-royalty sublicensing revenues, a high single-digit to low double-digit percentage of such revenues would be due and payable to Cedars, with the actual percentage of such revenues dependent on the stage of FDA authorization at the time the sublicense revenue is generated.

Enviro was also required to pay Cedars in connection with achieving the following Payment Milestones relating to products derived from the patent rights: successful completion of a Phase I clinical trial; successful completion of a Phase II clinical trial, receipt of FDA approval, and approval for a Phase III clinical trial; FDA approval of an NDA or BLA; cumulative net sales exceeding $50,000; and cumulative net sales exceeding $100,000. If all of these payment milestones are met among both of the Exclusive License Agreements, the required milestone payments would total in the mid-to-high seven-figures.

Pursuant to the Exclusive License Agreements, Enviro was obligated to meet the following Commercialization Milestones. Pursuant to the Enviro-Cedars License Agreement (Endoglin Antagonism), Enviro was obligated to (1) obtain an IND for a patent product within 1 year of the effective date of the agreement, (2) commence a Phase II trial within 2 years of the effective date of the agreement, and (3) submit an NDA or BLA to the FDA or equivalent regulatory agency in another jurisdiction within 7 years of the effective date of the agreement. Pursuant to the Enviro-Cedars License Agreement (Mitochondrial DNA), Enviro was obligated to (1) complete preclinical studies of a patent product within 2 years of the effective date of the agreement, (2) complete toxicology studies within 2.5 years of the effective date of the agreement, (3) obtain IND within 3 years of the effective date of the agreement, (4) begin a Phase I trial within 4 years of the effective date of the agreement, and (5) submit an NDA or BLA to the FDA or equivalent regulatory agency in another jurisdiction within 7 years of the effective date of the agreement. If the Commercialization Milestones are not met or extended, Cedars may convert the exclusive licenses into non-exclusive licenses or to a co-exclusive licenses or terminate the licenses.

The Exclusive License Agreements will, unless sooner terminated, continue in effect on a country-by-country basis until the last of the patents covering the patent rights or future patent rights expires. Under the terms of the Enviro-Cedars License Agreements, unless waived by Cedars, the agreements would automatically terminate: (a) if Enviro ceases, dissolves or winds up its business operations; (b) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of Cedars or the agreement is deemed illegal by a governmental body; (c) within 30 days for non-payment of royalties or if Enviro fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (d) within 60 days of Cedars' failure to cure any breach or default of a material obligation under the agreements; (e) within 90 days of Enviro's failure to cure any breach or default of a material obligation under the agreements; or (f) upon mutual written agreement of the parties.

Novation Agreements

On October 1, 2025, the Board of Directors approved the entry of Kairos and Enviro into a novation agreement (the "Cedars Novation Agreement") with Cedars. The Cedars Novation Agreement was entered into on October 1, 2025, but effective as of April 17, 2025, for purposes of transferring the exclusive license of two patents from Enviro, as the original licensee, to Kairos, as the new licensee. As the new licensee of the two patents, Kairos accepted and assumed all obligations and liabilities that may arise under the Exclusive License Agreements from Enviro and Enviro is relieved of all of its liabilities and obligations under the license agreements.

In addition, on October 1, 2025, the Board approved the Company's entry into a novation agreement (the "Tracon Novation Agreement") with Tracon Pharmaceuticals, Inc. (the "Tracon") and Enviro pursuant to which Enviro's rights and obligations under the license and supply agreement between Tracon, Enviro and Kairos, originally dated May 21, 2021, as amended to date (the "Tracon License Agreement"), were transferred from Enviro to Kairos and Enviro was relieved of any further liabilities or obligations under the license and supply agreement. Under the Tracon License Agreement, Tracon had granted Enviro exclusive access to its TRC105 and CD105 technologies, which Kairos has now assumed pursuant to the Tracon Novation Agreement.

Agreement with Lonza Sales AG

On November 12, 2025, the Company entered into an amendment (the "Lonza Amendment") to the sales agreement with Lonza Sales AG ("Lonza"), originally dated February 14, 2008, pursuant to which the Company agreed to purchase and Lonza agreed to testing of standards and the preparation to manufacture ENV105 antibody to be used in the Company's Phase 2 clinical trial. The Company agreed to pay a total of $1,143 in consideration, which will be paid over time as each of the 13 stages of the Lonza Amendment are completed. As of December 31, 2025, Lonza's testing and preparation of the ENV105 antibody had yet to be completed and the Company had yet to make any payments to Lonza.

Legal Matters

To the Company's knowledge, it is not currently the subject of any material legal proceeding. In the future, the Company may be involved in actual and/or threatened legal proceedings, claims, investigations and government inquiries arising in the ordinary course of our business, including legal proceedings, claims, investigations and government inquiries involving intellectual property, data privacy and security, other torts, illegal or objectionable content, consumer protection, securities, employment, contractual rights, civil rights infringement, false or misleading advertising, or other legal claims relating to our business.

NOTE 7 – INCOME TAXES

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. A full valuation allowance is established against all net deferred tax assets as of December 31, 2025 and 2024 based on estimates of recoverability. While the Company has optimistic plans for its business strategy, it determined that such a valuation allowance was necessary given the current and expected near-term losses and the uncertainty with respect to its ability to generate sufficient profits from its business model. Because of the impacts of the valuation allowance, there was no income tax expense or benefit for the years ended December 31, 2025 and 2024.

A reconciliation of the differences between the effective and statutory income tax rates for the years ended December 31, 2025 and 2024 are shown below:

	2025		2024	
	Amount	Percent	Amount	Percent
Federal statutory rates	$ (1,144)	21.0%	$ (547)	21.0%
State income taxes	(381)	7.0%	(182)	7.0%
Other	-	-%	(13)	0.5%
Valuation allowance against net deferred tax assets	1,525	(28.0)%	742	(28.5)%
Effective rate	$ -	-%	$ -	-%

At December 31, 2024 and 2023, the significant components of the deferred tax assets are summarized below:

	2025	2024
Deferred income tax assets:		
Net operating loss carryforwards	$ 2,766	$ 1,199
Capitalized R&D expenses	482	90
Total deferred income tax assets	3,248	1,289
Less: valuation allowance	(3,009)	(841)
Total net deferred income taxes	239	448
Deferred income tax liabilities:		
Amortization of intangibles	(17)	(62)
Accrual to cash	(222)	(386)
Total deferred income tax liabilities	(239)	(448)
Total deferred income tax assets	$ -	$ -

As of December 31, 2025, the Company has net operating loss (“NOL”) carryforwards of approximately $9,900 and are subject to IRS code section 382 limitations. Of the total federal net operating loss, approximately $9,600 has an indefinite carryforward period as of December 31, 2025. The remaining federal and California net operating loss carryforwards will expire through December 31, 2045, unless previously utilized. NOL carryforwards may be subject to limitation under Sections 382 of the Internal Revenue Code, and similar state provisions which limit the amount carryforwards that can be utilized to offset future taxable income. In general, an ownership change, as defined by Sections 382, results from transactions increasing ownership of certain stockholders in the stock of the corporation by more than 50 percentage points over a three-year period. The Company does not anticipate performing a complete analysis of the limitation on the annual use of the net operating loss carryforwards until the time that it anticipates it will be able to utilize these tax attributes. This could impose an annual limit or reduction on the Company’s ability to utilize net operating loss carryforwards and could cause U.S. federal income taxes to be paid earlier than otherwise would be paid if such limitations were not in effect. The U.S. federal net operating loss carryforwards are stated before any such anticipated limitations. If a change in ownership were to have occurred, the Company’s NOL carryforwards could be eliminated or restricted.

NOTE 8 – GAIN ON SETTLEMENT OF ACCOUNTS PAYABLE

On October 17, 2024, the Company entered into a Settlement Agreement with the Company’s former outside legal counsel. In connection with the agreement, the law firm agreed to settle the amount the Company owed them, which totaled $749, in exchange for a payment of $150. This resulted in a gain of $599 for the Company. In October 2024, the Company made the $150 payment to the law firm. As of December 31, 2024, no amounts were owed to the law firm.

NOTE 9 – SEGMENT INFORMATION

The Company operates and manages its business as one reportable segment and operates as a clinical-stage biopharmaceutical company. The Company's current focus is on developing immunotherapy and cell therapies for the treatment of cancer. The Company's Chief Operating Decision Maker ("CODM") is the Chief Executive Officer, who reviews financial information presented and decides how to allocate resources based on net income (loss). Net income (loss) is used for evaluating financial performance.

Significant segment expenses include research and development, officer compensation, insurance, and stock-based compensation. Operating expenses include all the remaining costs necessary to operate our business, which primarily include external professional services and other administrative expenses. The following table presents the significant segment expenses and other segment items regularly reviewed by our CODM:

	Years ended December 31,	
	2025	2024
Revenue	$ —	$ —
Less:		
Research and development, less officer compensation	1,837	414
Officer compensation and wages	716	119
Insurance	385	151
Stock-based compensation	482	218
Operating expenses	2,152	1,441
Other income (expenses)	125	(260)
NET LOSS	$ (5,447)	$ (2,603)

NOTE 10 – SUBSEQUENT EVENTS

In January 2026, the Company filed a shelf registration statement on Form S-3 (SEC File No. 333-292686) registering up to $75 million in aggregate securities and, in conjunction therewith, filed a prospectus supplement for the sale of up to $4.5 million of common stock pursuant to an At the Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright and Co., LLC (the "Placement Agent"). Under the ATM Agreement, the Placement Agent will be entitled to 3.0% of the gross proceeds of any sales made under the ATM Agreement. As a result of the ATM offering, subsequent to December 31, 2025, the Company raised $385 through the sale of 589,845 shares of its common stock.

On March 2, 2026, the Company entered into a binding term sheet with Celyn Therapeutics, Inc., a privately held biotechnology company, regarding a proposed asset acquisition of CL-273, an investigational, reversible, wild type sparing pan EGFR small molecule inhibitor being developed by Eilean Therapeutics for EGFR mutant non-small cell lung cancer. Pursuant to the term sheet, the Company will receive 100% of the development, manufacturing, commercialization rights, patent prosecution and patent filing rights worldwide to CL-273 in exchange for upfront payment of 16.5% of the Company's outstanding capital stock, with such stock to be issued in the form of Common Stock or convertible preferred stock, and milestone payments of (i) $15 million payable at NDA or BLA FDA, with such payment to be made in combination of cash and stock and (ii) 2% royalties from net revenue generated from sales in the U.S. for the life of the intellectual property. Closing is subject to satisfactory completion of due diligence and negotiation of a definitive acquisition agreement.

On March 27, 2026, the Company entered into an additional statement of work to the sales agreement with Lonza Sales AG ("Lonza"), originally dated February 14, 2008, pursuant to which the Company agreed to purchase and Lonza agreed to testing of standards and the preparation to manufacture ENV105 antibody to be used in the Company's Phase 2 clinical trial. The Company agreed to pay an approximate total of $2,000 in consideration, which will be paid over time as each of the 13 stages of the Lonza Amendment are completed. See Note 6 for further details.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

As discussed in Form 8-K filed with the SEC on April 28, 2025 (the "Form 8-K"), which is incorporated herein by reference，on April 23, 2025, the Audit Committee of the Company selected Weinberg and Company, P.A. ("Weinberg") to serve as the Company's independent registered public accounting firm for the review of its Quarterly Reports on Form 10-Q and Annual Report on Form 10-K for the fiscal year ending December 31, 2025. As a result, the Audit Committee dismissed Marcum LLP ("Marcum") and Marcum would no longer serve as the Company's independent registered public accounting firm, effective as of April 23, 2025.

Marcum's audit report on our financial statements for the years ended December 31, 2024 and 2023 contained no adverse opinion or disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope or accounting principles, except that the audit report on the financial statements of the Company for the year ended December 31, 2023 was modified as to contain uncertainty about the Company's ability to continue as a going concern.

For the years ended December 31, 2024 and 2023 and through the date of the Form 8-K, the Company had no "disagreements" (as defined in Regulation S-K, Item 304(a)(1)(iv) and the related instructions) with Marcum on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements if not resolved to the satisfaction of Marcum would have caused them to make reference thereto in their reports on the financial statements for such periods.

There were no reportable events as defined in item 304(a)(1)(v) of Regulation S-K for the years ended December 31, 2024 or 2023 except for the material weaknesses in internal control over financial reporting for the fiscal years ended December 31, 2024 and 2023, as disclosed in Part II, Item 9A of the Company's Annual Report on Form 10-K for the years ended December 31, 2024 and 2023.

For the years ended December 31, 2024 and 2023, prior to retaining Weinberg, the Company did not consult with Weinberg regarding either: (i) the application of accounting principles to a specified transaction, either contemplated or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, and neither a written report nor oral advice was provided to the Company that Weinberg concluded was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issue; or (ii) any matter that was the subject of a "disagreement" or a "reportable event" (as those terms are defined in Item 304(a)(1)(iv) and (a)(1)(v) of Regulation S-K, respectively).

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow for timely decisions regarding required disclosure. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2025. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of December 31, 2025.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Management's Annual Report on Internal Control over Financial Reporting

As of December 31, 2025, our management carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. Such evaluation was carried out by our Chief Financial Officer under the supervision of our Chief Executive Officer. Based on this evaluation, management concluded that our disclosure controls and procedures were, and continue to be, ineffective as of December 31, 2025. Based on the foregoing, our management concluded that our internal controls over the following financial reporting areas to be material weaknesses:

- Due to our size and stage of development, segregation of all conflicting duties is not always possible or economically feasible. During the year, we lacked sufficient review procedures and segregation of duties such that proper review had not been performed by someone other than the preparer, including manual journal entries, and that process documentation is lacking for review and monitoring controls over the financial statements closing process.

There have been no changes in the Company's internal control over financial reporting during the three months ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. Management will continue to monitor and evaluate the effectiveness of our internal controls and procedures over financial reporting as necessary.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act) that occurred during the period covered by this Annual Report that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. However, the Company will continue to monitor and work to address the underlying causes of material weaknesses and control deficiencies. Such material weaknesses and control deficiencies will not be fully remediated until the Company has concluded that its internal controls are operating effectively for a sufficient period of time.

ITEM 9B. OTHER INFORMATION

10b5-1 Plan

On December 16, 2025, John S. Yu, the Company's Chief Executive Officer and Chairman of the Board of Directors, adopted a Rule 10b5-1 trading plan. Mr. Yu's Rule 10b5-1 trading plan is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) and provides for the potential sale of up to 3,500,000 shares of the Company's common stock at specified limit prices ranging from $2.50 to $8.00 per share from March 16, 2026 to December 31, 2026.

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

Set forth in the table below are the name, age, title of each executive officer and director, followed by a detailed description of their business experience and qualifications.

Name	Age	Position(s)
John S. Yu, M.D.	61	Chief Executive Officer and Chairman of the Board
Neil Bhowmick, Ph.D.	54	Chief Scientific Officer
Ramachandran Murali. Ph.D.	65	Vice President of Research and Development
Doug Samuelson	66	Chief Financial Officer
Hyun W. Bae, M.D.	56	Independent Director
Hansoo Michael Keyoung, M.D., Ph.D.	51	Independent Director
Rahul Singhvi, Sc.D., MBA	60	Independent Director

John S. Yu, M.D., CEO and Chairman of the Board of Directors

Dr. Yu, our co-founder, Chairman and Chief Executive Officer, is a medical clinician and investigator. Since 2019, Dr. Yu has also served as the Chief Financial Officer and a director of our wholly owned subsidiary, Enviro. Dr. Yu is committed to advancing Kairos's pipeline to tackle the most unmet needs in cancer: resistance to cancer therapeutics and the suppressed immune response in cancer. As the Professor of Neurosurgery and Director of Surgical Neuro-Oncology at Cedars-Sinai Medical Center, where he has worked since January 1998 until present, he has dedicated his medical career to the development of immunotherapy for cancer and glioblastoma. Dr. Yu is the co-inventor of the GITR and activated T cell technology. Dr. Yu earned his bachelor's degree from Stanford University in 1985 and spent a year at the Sorbonne in Paris studying French literature while completing a fellowship in immunology at the Institut Pasteur in Paris, and earned his medical degree from Harvard Medical School in 1990 and a master's degree from the Harvard University Department of Genetics in 1990, before pursuing a neurosurgical residency at Massachusetts General Hospital in Boston. His portfolio has included 26 research grants, 10 patents, seven FDA-approved investigational drugs and 17 IRB approved clinical trials. We believe Dr. Yu, with his substantial experience in cancer research as both a clinician and investigator, is qualified to serve on our board of directors.

Neil Bhowmick, Ph.D., Chief Scientific Officer

Dr. Bhowmick, our Chief Scientific Officer, has more than 20 years of broad biochemistry experience filing and prosecuting patents in therapeutics and devices, published in peer-reviewed journals (110 publications) leading foundational and pre-clinical cancer studies, obtaining regulatory approvals, and conducting clinical trials. Dr. Bhowmick discovered the role of fibroblasts in cancer therapy resistance and has used this finding to extend the time of cancer remission in multiple cancer types in preclinical and clinical examples as a founder and CEO of Enviro Therapeutics Inc. He trained at Vanderbilt University and is the Professor of Medicine at Cedars-Sinai Medical Center and Director of the Cancer Biology Program at Cedars-Sinai Cancer. He is on the Editorial Board of four scientific journals and charter member of a NIH grant study section. Dr. Bhowmick was a Consultant at Celgene (currently Bristol Myers Squibb, a New York Stock Exchange-listed company) in 2009, Xencor Inc., a Nasdaq-listed company, from 2019 to 2020 and at Tracon, a Nasdaq-listed company, from 2014 to 2019. He currently serves on the Scientific Advisory Board of FibroBiologics. Dr. Bhowmick has received NCI/NIH funding for over 15 years, has been cited over 15,000 times, and holds six patents for biomarker detection platforms and stromal targeted therapeutics (inclusive of ENV 105 and ENV 205**).**

Ramachandran Murali, Ph.D., Vice President of Research and Development

Dr. Murali, our Vice President of Research and Development, is an established structural biologist with expertise in macromolecular crystallography, computational biology, drug discovery, immunology, and cancer biology. Using these skills, Dr. Murali advanced a unique technology for creating small peptidomimetics and small molecule drugs that target protein-protein/DNA interactions for diagnostic and therapeutic applications in areas like cancer biology, immunotherapy, and autoimmune pathologies. Dr. Murali co-founded three biotech startup companies, including Xcyte Therapeutics, a cancer immunotherapy company founded in Seattle, WA in 1996, Ception Therapeutics, Inc, an immunotherapeutic pharmaceutical company founded in Philadelphia, PA in 2003 and Nidus, CA, a immunotherapeutic company founded in Los Angeles, CA in 2005. Dr. Murali's accomplishments also include developing small molecule agonist/antagonists for numerous cell surface receptor complexes, including members of the TNFR super family. Recently, he targeted various transcription factors, such as Onecut-2, for cancer therapy. Dr. Murali has over 10 years of experience in collaborating with several biotech companies and is a co-inventor of more than 10 patents. Dr. Murali obtained his doctoral degree in Biophysics from the University of Madras, one of the pioneering institutes for structural biology in India. Upon graduation, he completed his post-doctoral training at Columbia University and the Wistar Institute (Philadelphia, PA). Later, he joined the University of Pennsylvania as a faculty member and rose to the position of Associate Professor. He is currently a Professor in the Department of Biomedical Sciences, Research Division of Immunology at Cedars-Sinai Medical Center (Los Angeles, CA).

Doug Samuelson, Chief Financial Officer

Mr. Samuelson has served as our external Chief Financial Officer since 2019. Mr. Samuelson is a finance and accounting professional with over 25 years of experience. From 2016 to 2022, Mr. Samuelson served as the Chief Financial Officer of Wellness Center USA, Inc. in Tucson, Arizona. From 2016 to March 2020, Mr. Samuelson served as the Director of Accounting of Second Sight Medical Products, Inc., and in this position, managed all accounting functions, including all general ledger close functions, tax reporting, external audit responsibilities, banking and technical accounting issues. From 2018 to 2019, Mr. Samuelson served as the Chief Financial Officer of AdvaVet, Inc., in Los Angeles, California, the U.S. subsidiary of Swedish pharmaceutical company, Oasmia Pharmaceutical AB (NASDAQ: OASM). From 2016 to 2018, Mr. Samuelson was the Chief Financial Officer of Solis Tek, Inc. (OTC: GNAL), where he handled all financial reporting with the SEC. Mr. Samuelson obtained a Bachelor of Science in Accounting from University of Utah, College of Business, and obtained a Master of Science in Computer Science from California State University, Northridge, School of Engineering. He is also a Certified Public Accountant in the State of California.

Hyun W. Bae, M.D., Independent Director

Dr. Hyun W. Bae has served on our board of directors as an independent director since September 9, 2020. Dr. Bae is an orthopaedic surgeon in private practice in Santa Monica, California, and has been appointed Professor in Orthopaedic Surgery at Cedars-Sinai Medical Center, the Director of Cedars' Education and Fellowship program, and a clinical partner of the Orthopaedic Stem Cell and Tissue Engineering Laboratory. Since 2010, Dr. Bae has served as the Chief Medical Officer and a director of Prosidyan, a company that develops proprietary fiber-based bioactive glass products. Dr. Bae has served as a Scientific Advisory Board Member of Mesoblast since 2008, Engage Surgical since 2018, and Spine Biopharma since 2019. He also served as a Scientific Advisory Board Member of Tissuegene from 2008 to 2015. Dr. Bae is a 20-year veteran of the drug development industry and is a renowned researcher and inventor. He was principal investigator for four FDA-approved randomized clinical trials and has completed 30 clinical studies throughout his career. Dr. Bae also has authored 60 published scientific papers, written five review articles and holds 30 patents. Dr. Bae obtained a Biomechanics degree from Columbia University and a Doctor of Medicine degree, cum laude, from Yale University and is a former NIH Howard Hughes Research Fellow in Bethesda, Maryland. We believe that Dr. Bae is qualified to serve on our board of directors because of his industry and technical experience, including his operational experience in drug discovery and development, and service on multiple company boards.

Hansoo Michael Keyoung, M.D., Ph.D., Independent Director

Dr. Hansoo Michael Keyoung has served on our board of directors as an independent director since our IPO in September 2024. For over 20 years, Dr. Keyoung has led a successful career as a physician, healthcare executive, and investor in the United States, Europe and Asia. Since 2017, Dr. Keyoung has served as the head of North America for CBC Group, a healthcare-dedicated private equity firm with over $4 billion in assets under management. He has served as Board Chair of AffaMed Therapeutics since 2019, a director of Graybug Vision, a Nasdaq-listed company, since 2019, and a director of InxMed since 2019. From 2015 to 2017, Dr. Keyoung also served as the Chief Executive Officer of Genexine, a KOSDAQ-listed biotech company with a $1 billion plus market cap focused on developing innovative biologic drugs for cancer and rare diseases. During his tenure as Chief Executive Officer of Genexine, he successfully helped lead clinical development in Europe and Asia, raised $100 million in equity, and set up partnerships with Merck, Fosun Pharma, Tasly Pharma, and Kalbe Pharma. From 2013 to 2015, he also served as President of Catalyst Biosciences, a Nasdaq-listed company and a clinical-stage hemophilia and ophthalmology company that partnered with Pfizer, MedImmune, and Isu Abxis. Additionally, he has experience advising Eli Lilly, Bausch & Lomb, and Samsung Electronics/Biologics on Asian expansion, global drug development and commercial partnership strategies. Dr. Keyoung has a Doctor of Medicine degree and a Doctor of Philosophy degree in neuroscience and neurology from Cornell University Weill Medical College and Memorial Sloan Kettering. He was also a Biomedical Fellow at Rockefeller University and Memorial Sloan Kettering. We believe that Dr. Keyoung is qualified to serve on our board of directors because of his extensive experience serving in management and on boards of directors of public company, his experience in private equity investing in healthcare companies, and his extensive advisory work to industry-leading healthcare companies.

Rahul Singhvi, Sc.D., MBA, Independent Director

Dr. Rahul Singhvi has served on our board of directors as an independent director since December 10, 2024. Dr. Singhvi is a global leader in the Life Sciences industry and is cofounder of the US based biomanufacturing company, Resilience (National Resilience, Inc.). Prior to cofounding Resilience in 2020, from October 2019 to July 2020, Dr. Singhvi was an Operating Partner at Flagship Pioneering, where he founded and operated companies launched from Flagship's innovation foundry, Flagship Venture Labs. Before joining Flagship, from September 2013 until October 2019, Rahul was the Chief Operating Officer at the Vaccine Business Unit of Takeda Pharmaceutical Co Ltd. (NYSE: TAK) where he led worldwide vaccine manufacturing operations. Before joining Takeda, from August 2005 to April 2011, Dr. Singhvi was President and CEO of Novavax, Inc. (Nasdaq:NVAX) where he led the company's transformation into a global vaccine player. Dr. Singhvi's career began at Merck & Co in 1994, where he held several positions in R&D and manufacturing. Dr. Singhvi serves on the Board of Trustees of the Keck Graduate Institute, and on the Board of Directors for Codexis (Nasdaq:CDXS), and Garuda Therapeutics (private). Dr. Singhvi graduated as the top ranked chemical engineer from the Indian Institute of Technology, Kanpur, India and obtained both his M.S. and Sc.D. degrees in chemical engineering from MIT. He received an MBA from the Wharton School of the University of Pennsylvania, where he graduated as a Palmer Scholar. Because of Dr. Signhvi's experience and knowledge in the operation and leadership of early-stage public healthcare companies, we believe he will be able to provide valuable insights and contributions to our Board.

Family Relationships

There are no family relationships among our directors and executive officers.

Composition of Our Board of Directors

Our business and affairs are organized under the direction of our board of directors, which consists of four members, each of whom are elected to serve for one year terms to hold office until the next annual meeting of our stockholders and until a successor is appointed and qualified, or until their removal, resignation, or death. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counselling, and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Director Independence

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning her or his background, employment and affiliations, including family relationships, our board of directors has determined that three of our four directors, each of Drs. Bae, Keyoung and Singhvi, are "independent" directors in accordance with the rules and regulations of NYSE American.

Involvement in Certain Legal Proceedings

To the best of our knowledge, none of our directors or executive officers has, during the past ten years:

- been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offences);
- had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;
- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;
- been found by a court of competent jurisdiction in a civil action or by the Securities and Exchange Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;
- been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
- been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act (15 U.S.C. 78c(a)(26))), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act (7 U.S.C. 1(a)(29))), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

The Board of Directors' Role in Risk Oversight

The board of directors oversees that the assets of our Company are properly safeguarded, that the appropriate financial and other controls are maintained, and that our business is conducted wisely and in compliance with applicable laws and regulations and proper governance. Included in these responsibilities is the board of directors' oversight of the various risks facing our company. In this regard, our board of directors seeks to understand and oversee critical business risks. Our board of directors does not view risk in isolation. Risks are considered in virtually every business decision and as part of our business strategy. Our board of directors recognizes that it is neither possible nor prudent to eliminate all risk. Indeed, purposeful and appropriate risk-taking is essential for our company to be competitive on a global basis and to achieve its objectives.

While the board of directors oversees risk management, company management is charged with managing risk. Management communicates routinely with the board of directors and individual directors on the significant risks identified and how they are being managed. Directors are free to, and indeed often do, communicate directly with senior management.

Our board of directors administers its risk oversight function as a whole by making risk oversight a matter of collective consideration; however, much of the work is delegated to committees, which will meet regularly and report back to the full board of directors. We have established a standing audit committee, compensation committee and nominating and corporate governance committee of our board of directors. The audit committee will oversee risks related to our financial statements, the financial reporting process, accounting and legal matters, the compensation committee will evaluate the risks and rewards associated with our compensation philosophy and programs, and the nominating and corporate governance committee will evaluate risk associated with management decisions and strategic direction.

Committees of Our Board of Directors

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which is made up of independent directors. 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 NYSE American rules and regulations, which have been posted to our website at https://kairospharma.com. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

Our audit committee consists of Dr. Michael Keyoung, Dr. Hyun W. Bae and Dr. Rahul Singhvi, each of whom our board of directors has determined satisfies the independence requirements under the NYSE American rule and regulations and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee is Dr. Michael Keyoung, whom our board of directors has determined is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control and financial-statement audits, and to oversee our independent registered accounting firm. Specific responsibilities of our audit committee include:

- helping our board of directors oversee our corporate accounting and financial reporting processes;
- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

Compensation Committee

Our compensation committee consists of Dr. Singhvi, Dr. Keyoung and Dr. Bae. The chair of our compensation committee is Dr. Singhvi. Our board of directors has determined that each member of our compensation committee is independent under the NYSE American rules and regulations and as a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans and programs, and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate. Specific responsibilities of our compensation committee include:

- reviewing and approving the compensation of our chief executive officer, other executive officers, and senior management;
- reviewing and recommending to our board of directors the compensation paid to our directors;
- reviewing and approving the compensation arrangements with our executive officers and other senior management;
- administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending, and terminating, incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans, change-of-control protections, and any other compensatory arrangements for our executive officers and other senior management;
- reviewing, evaluating, and recommending to our board of directors' succession plans for our executive officers; and
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation strategy, including base salary, incentive compensation, and equity-based grants, to assure that it promotes stockholder interests and supports our strategic and tactical objectives, and that it provides for appropriate rewards and incentives for our management and employees.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Dr. Singhvi, Dr. Bae and Dr. Keyoung. The chair of our nominating and corporate governance committee is Dr. Singhvi. Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the NYSE American rules and regulations, a non-employee director, and free from any relationship that would interfere with the exercise of his or her independent judgment.

Specific responsibilities of our nominating and corporate governance committee include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our board of directors;
- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- instituting plans or programs for the continuing education of our board of directors and orientation of new directors;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the board of directors' performance, including committees of the board of directors and management.

Stockholders of record may also nominate director candidates for our annual meetings of stockholders by following the procedures set forth in our bylaws.

Code of Business Conduct and Ethics

We have adopted a written Code of Business Conduct and Ethics that applies to all our employees, 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 our Code of Business Conduct and Ethics has been posted on our website at www.kairospharma.com. We intend to disclose on our website any future amendments of our Code of Business Conduct and Ethics 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 Business Conduct and Ethics. Information contained on, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

Insider Trading Policy

We have adopted an insider trading policy which prohibits our directors, officers and employees from engaging in transactions in our common stock while in the possession of material non-public information; engaging in transactions in the stock of other companies while in possession of material non-public information that they become aware of in performing their duties; and disclosing material non-public information to unauthorized persons outside our company.

Our insider trading policy restricts trading by directors, officers and certain key employees during blackout periods, which generally begin three weeks prior to the last day of each fiscal quarter and ending three business days following the date the Company's financial results are publicly disclosed and the Form 10-Q or the Form 10-K is filed. Additional blackout periods may be imposed with or without notice, as the circumstances require.

In addition, directors, officers and employees are expressly prohibited from making certain transactions, including short-term trading, short sales, options trading, trading on margin, and hedging, unless such transaction is specifically approved in advance by the administrator of our insider trading policy.

While we have not adopted a formal policy governing insider trading restrictions on the Company itself, as a matter of practice the Company observes the same procedures and restrictions, including the potential existence of material non-public information, with respect to transactions by the Company in its securities, including repurchases of common stock.

Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last calendar 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.

Non-Employee Director Compensation

Compensation for non-employee directors is determined by the board of directors. Each non-employee director receives an annual cash compensation of $50,000, payable in quarterly instalments in arrears, plus an additional $10,000 cash compensation for the chair of the audit committee. In addition, our policy provides that, upon initial election or appointment to our board of directors, each new non-employee director will be granted a one-time grant, or Director Initial Grant, of $50,000 of RSUs, with the number of RSUs issued calculated as of the grant date, which will vest in substantially equal annual instalments over a period of three years. The Director Initial Grant is subject to full acceleration of vesting upon the sale of our Company, in accordance with the terms of our 2023 Equity Incentive Plan. Employee directors receive no additional compensation for their service as a director.

We reimburse our directors for all reasonable out-of-pocket expenses incurred for their attendance at meetings of our board of directors or any committee thereof.

Our current non-employee directors earned the following compensation for their service during fiscal year ended December 31, 2025:

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)[3]	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
Hyun W. Bae[1]	$ 50,000	12,400	-	-	-	$ 62,400
Hansoo Michael Keyoung[1]	$ 60,000	12,400	-	-	-	$ 72,400
Rahul Singhvi[2]	$ 50,000	18,750	-	-	-	$ 68,750

(1) We entered into director agreements with Dr. Bae and Dr. Keyoung, effective September 16, 2024, the date of our initial listing on the NYSE American.

(2) We entered into a director agreement with Dr. Singhvi upon his appointment on December 10, 2024.

(3) Each non-employee director received RSUs which vest annually in one-third increments over a period of three years.

Our certificate of incorporation contains provisions limiting the liability of directors, and our bylaws provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our certificate of incorporation and bylaws will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board of directors. In addition, we have entered into indemnification agreements with each of our directors and executive officers, which will require us to indemnify them.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of our common stock, to file reports regarding ownership of, and transactions in, our securities with the SEC and to provide us with copies of those filings.

To the Company's knowledge, based solely on our review of the copies of such forms furnished to us and written representations by our officers and directors regarding their compliance with applicable reporting requirements under Section 16(a) of the Exchange Act, we believe that all Section 16(a) filing requirements for our executive officers, directors and 10% stockholders were met during the year ended December 31, 2025, except for the following:

Name	Late Reports	Date of Earliest Transaction	Date Filed
John S Yu	Form 4	01/01/2025	02/24/2025
	Form 4	10/08/2025	11/26/2025
Ramachandran Murali	Form 4	01/01/2025	02/24/2025
	Form 4	10/08/2025	11/26/2025
Neil Bhowmick	Form 4	01/01/2025	04/07/2025
	Form 4	10/08/2025	12/30/2025
Doug Samuelson	Form 4	10/08/2025	11/26/2025
Rahul Singhvi	Form 4	10/08/2025	11/26/2025
Michael Hansoo Keyoung	Form 4	09/16/2025	11/26/2025
Hyun W. Bae	Form 4	09/16/2025	12/23/2025

ITEM 11 - EXECUTIVE COMPENSATION

Our named executive officers for the years ended December 31, 2025 and 2024 were Dr. Yu, Dr. Bhowmick, Dr. Murali and Mr. Samuelson.

Summary Compensation Table

Set forth below is the summary compensation table for our named executive officers for the years ended December 31, 2024 and 2025. We are currently a "emerging growth company" and a "smaller reporting company" as defined under SEC rules and, as a result, we are required to include only two years of compensation disclosure, rather than three years, in this table.

Name and principal position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
John S. Yu	2024	51,301	-	34,440	-	-	-	-	85,741
	2025	200,000	87,500	75,415					362,915
Neil Bhowmick	2024	29,315	-	34,440	-	-	-	-	72,755
	2025	106,250	50,000	69,165					225,415
Ramachandran Murali	2024	23,452	-	34,440	-	-	-	-	63,892
	2025	87,500	40,000	62,915					190,415
Doug Samuelson	2024	14,657		123,000	-	-	-	-	137,657
	2025	62,500	50,000	142,250					254,750

Employment Agreements

Each of our executive officers has entered into an employment agreement with us. The executive officers will each receive compensation on an annual basis in cash, payable in monthly installments commencing at the completion of our IPO, as well as an initial restricted stock grant of RSUs. As may be decided from time to time by our Compensation Committee, our executive officers may be entitled to various target bonuses. The terms of the employment agreements are as follows:

Employment Agreement with John Yu, MD

On September 27, 2023, we entered enter into an employment agreement with our Chief Executive Officer and Chairman of the Board, John Yu, M.D. Dr. Yu's employment agreement became effective upon consummation of our IPO. Under the terms of his employment agreement, Dr. Yu will receive base compensation of $175,000 per year. Dr. Yu also received 14,000 RSUs, which will vest annually in substantially equal installments over a period of three years. In addition, Dr. Yu will be entitled to receive an annual cash or stock bonus, as may be determined by the compensation committee of the board of directors. Should Dr. Yu terminate his employment for "Good Reason," as defined in his employment agreement, he will be entitled to his then applicable base salary for period of six months, subject to his continued compliance with certain requirements of his employment agreement. Dr. Yu will also be entitled to standard benefits that may be offered by the Company from time to time, including 30 days' paid vacation.

Employment Agreement with Doug Samuelson

On September 27, 2023, we entered into an employment agreement with our Chief Financial Officer, Mr. Doug Samuelson, which became effective upon consummation of our IPO. Under the employment agreement, Mr. Samuelson will be entitled to receive (i) a base salary equal to $50,000 per year, payable in monthly installments; (ii) an annual grant of 50,000 RSUs, which RSUs will be issued each year on the anniversary date of our IPO, with each grant becoming fully vested after 12 months; and (iii) such number of RSUs equal to 1.2 times the amount of outstanding invoices then owed to Mr. Samuelson according to his current consulting agreement, with such number of RSUs to be calculated at our IPO per share purchase price. In addition, in the event of "Change of Control," as such term is defined in his employment agreement, Mr. Samuelson will be entitled to receive 250,000 RSUs, which number shall include all RSUs Mr. Samuelson has received up until the date of the Change of Control, and which shall all vest immediately upon issuance. Mr. Samuelson will also be entitled to receive an annual cash or stock bonus, as may be determined by the compensation committee of the board of directors and will be entitled to standard benefits that may be offered by the Company from time to time, including 30 days' paid vacation and six months' severance in the event his employment is terminated without cause.

Employment Agreement with Neil Bhowmick, MD

On September 27, 2023, we entered into an employment agreement with our Chief Scientific Officer, Neil Bhowmick, M.D., which became effective upon the consummation of our IPO. Under Dr. Bhowmick's employment agreement, Dr. Bhowmick will receive a base salary equal to $100,000 per year, payable in monthly installments, and 14,000 RSUs, which RSUs will vest annually over a period of three years. In addition, Dr. Bhowmick will be entitled to receive an annual cash or stock bonus, as may be determined by the board of directors or a committee thereof. Dr. Bhowmick will also be entitled to standard benefits that may be offered by the Company from time to time, including 30 days' paid vacation and six months' severance in the event his employment is terminated without "Good Cause" in accordance with the terms of his employment agreement.

Employment Agreement with Ramachandran Murali, MD

On September 27, 2023, we entered into an employment agreement with our Vice President of Research and Development, Ramachandran Murali, MD, which became effective upon consummation of our IPO. Under Dr. Murali's employment agreement, Dr. Murali will receive base compensation of $80,000 per year and will receive an initial grant of 14,0000 RSUs, which RSUs will vest annually in substantially equal installments over a period of three years. In addition, Dr. Murali will be entitled to receive an annual cash or stock bonus, as may be determined by the board of directors or a committee thereof. Dr. Murali will also be entitled to standard benefits that may be offered by the Company from time to time, including 30 days' paid vacation and six months' severance in the event his employment is terminated without "Good Cause" in accordance with the terms of his employment agreement.

Equity-Based Incentive Awards

In July 2023, we adopted our 2023 Equity Incentive Plan, which reserved 1,650,000 shares of common stock for issuance under the 2023 Equity Incentive Plan. The equity-based incentive awards granted under the 2023 Equity Incentive Plan are designed to align our interests and those of our stockholders with those of our employees and consultants, including our executive officers. Our board of directors or an authorized committee thereof is responsible for approving equity grants.

Outstanding Equity Awards at Fiscal Year End

Outstanding Equity Awards

Outstanding Equity Awards at December 31, 2025

The following table provides information regarding outstanding equity awards held by our named executive officers as of December 31, 2025.

		Options				Restricted Stock Unit Awards	
Name	**Grant Date**	**Number of Securities Underlying Options (#) Vested**	**Number of Securities Underlying Options (#) Unvested**	**Option Exercise Price ($)**	**Option Expiration date**	**Number of Securities Underlying RSUs (#) Vested**	**Number of Securities Underlying RSUs (#) Unvested**
John S. Yu	10/08/2025	-	-	-	-	-	190,840
	09/16/2024	-	-	-	-	7,000	7,000
Doug Samuelson	10/08/2025	-	-	-	-	-	152,672
	09/16/2024	-	-	-	-	50,000	-
Neil Bhowmick	10/08/2025	-	-	-	-	-	171,756
	09/16/2024	-	-	-	-	7,000	7,000
Ramachandran Murali	10/08/2025	-	-	-	-	-	152,672
	09/16/2024	-	-	-	-	7,000	7,000

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act. As an emerging growth company we will be exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our chief executive officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Clawback Policy

As a public company, if we are required to restate our financial results due to our material noncompliance with any financial reporting requirements under the federal securities laws as a result of misconduct, the Chief Executive Officer and Chief Financial Officer may be legally required to reimburse our Company for any bonus or other incentive-based or equity-based compensation they receive in accordance with the provisions of section 304 of the Sarbanes-Oxley Act of 2002, as amended. As such, on March 1, 2024 we adopted a clawback policy, entitled, "Policy for Recovery of Erroneously Awarded Compensation."

ITEM 12 - SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information regarding beneficial ownership of our capital stock as of March 31, 2026 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors and 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 and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 21,411,198 shares of our common stock outstanding as of March 31, 2026.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is 2355 Westwood Blvd. #139, Los Angeles, California 90064.

Name of Beneficial Owner	Number of Shares Beneficially Owned (#) (2)	Percentage of Shares Beneficially Owned (%)
Greater than 5% Holders:		
Technomedics Management and Systems, Inc.[(1)]	1,139,027	5.3
Directors and Named Executive Officers:		
John S. Yu, M.D. [(3)]	5,347,170	25.0
Ramachandran Murali, Ph.D.	142,191	**
Neil Bhowmick, Ph.D.	1,135,316	5.3
Douglas Samuelson	140,367	**
Hyun W. Bae, M.D	49,855	**
Hansoo Michael Keyoung, M.D.	5,569	**
Rahul Singhvi, Sci.D., MBA	5,569	**
All directors and executive officers as a group (7 persons)	6,826,037	31.9

** Represents beneficial ownership of less than 1%.
(1) Manfred Mosk exercises voting and investment power of all shares held by Technomedics Management and Systems, Inc.
(2) Does not include restricted stock units issued under the Company's 2023 Equity Incentive Plan which remain subject to vesting.
(3) The Yu Family trust owns 5,316,572 shares and John Yu owns 30,598 shares of our common stock.

ITEM 13 - CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The following includes a summary of transactions since January 1, 2023 to which we have been a party in which the amount involved exceeded or will exceed the lesser of $120,000 as of December 31, 2025, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Executive Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

Loans and Advances from Related Parties

In August 2024, the Company borrowed $0.04 million from one of its officers. The loans accrue interest at 7.5% interest per annum, are unsecured, and are due in August 2025.

In April and May 2024, the Company borrowed $0.1 million from three of its officers. The loans accrue interest at 7.5% per annum, are unsecured, and are due in April 2025. The officers holding notes payable have since agreed to convert the outstanding loans and principal into shares of common stock of the company, converting at the IPO per share purchase price, following completion of the IPO.

During the year ended December 31, 2021, stockholders of the Company, and a company whose principal stockholder is also a stockholder of the Company, advanced the Company $0.01 million, which was all outstanding at December 31, 2021. The advances accrue no interest, are unsecured and are due on demand. As of December 31, 2021, $0.01 million was owed on the advances. During the year ended December 31, 2022, the Company repaid $0.01 million of the advances, and as of December 31, 2022 and 2023, and June 30, 2024, a total of $0.004 was outstanding.

Policies and Procedures for Transactions with Related Persons

Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds $120,000 (or, if less, 1% of the average of our total assets in a fiscal year) and such person would have a direct or indirect interest, must be presented to our board of directors or our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our board of directors or our audit committee is to consider the material facts of the transaction, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

ITEM 14 - PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Auditors

The following table represents fees for professional audit services for the audit of the Company's annual financial statements for the fiscal years ended December 31, 2025 and 2024, rendered by Weinberg and Company, P.A., the Company's current independent registered public accounting firm, and Marcum LLP, the Company's prior independent registered public accounting firm.

	Weinberg and Company, P.A.		Marcum LLP	
(in thousands)	**Fiscal year ended December 31,**		**Fiscal year ended December 31**	
	2025	**2024**	**2025**	**2024**
Audit fees [1]	$ 50,150	-	$ 10,000	144,200
Audit-related fees [2]	-	-	16,000	59,740
Tax fees	-	-	-	-
All other fees	-	-	-	-
Total fees	$ 50,150	-	26,000	203,940

(1) Audit fees consist of fees for the audit of the Company's annual financial statements for 2024 and 2025 and services in connection with registration statements filed in 2024 and 2025. Audit fees also include fees related to the reviews of interim financial information included in Forms 10-Q and for consent or comfort letter procedures performed in conjunction with registration statements or completing financial transactions during the respective fiscal years.

Audit Committee Pre-approval Policies

Our policy has been for the Audit Committee to pre-approve all audit, audit-related and non-audit services performed by our independent auditors and to subsequently review the actual fees and expenses paid to our independent auditors. Accordingly, the Audit Committee pre-approved all audit, audit-related and non-audit services performed by our independent auditors and subsequently reviewed the actual fees and expenses paid to our former auditor, Marcum LLP, during fiscal 2023 and 2024 and the actual fees and expenses paid to our current auditor, Weinberg and Company, P.A. during fiscal year 2025.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibit Number	Description
1.1	At the Market Offering Agreement, dated January 12, 2026, by and between Kairos Pharma,Ltd. and H.C. Wainright Co., LLC (incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 filed on January 12, 2026).
3.1	Certificate of Incorporation of Kairos Pharma, Ltd. filed with the Secretary of State of the State of Delaware, dated May 10, 2023 (incorporated by reference to Exhibit 3.5 to the Company's Registration Statement on Form S-1, filed on August 16, 2024).
3.2	Bylaws of Kairos Pharma, Ltd. (Delaware) (incorporated by reference to Exhibit 3.6 to the Company's Registration Statement on Form S-1, filed on August 16, 2024).
4.1	Form of Representative's Warrant (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1, filed on August 16, 2024).
4.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed January 14, 2025).
4.3	Form of Common Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed January 17, 2025).
4.4	Form of Placement Agent Warrants (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed January 17, 2025).
4.5	Description of Securities (incorporated by reference to Exhibit 4.5 to the Company's Amendment No. 1 to its Annual Report on Form 10-K/A filed April 28, 2025)
10.1	Exclusive Option Agreement, dated March 16, 2020, between Cedars-Sinai Medical Center and Enviro Therapeutics, Inc. (re Depletion of Mitochondrial DNA) (incorporated by reference to Exhibit 10.1 to the Registration Statement filed on August 16, 2024).
10.2	Amendment to Exclusive Option Agreement, dated January 11, 2021, between Cedars-Sinai Medical Center and Enviro Therapeutics, Inc. (re Depletion of Mitochondrial DNA). (incorporated by reference to Exhibit 10.2 to the Registration Statement filed on August 16, 2024).
10.3	Exclusive Option Agreement, dated March 16, 202, between Cedars-Sinai Medical Center and Enviro Therapeutics, Inc. (re Sensitization of Solid Tumors) (incorporated by reference to Exhibit 10.3 to the Registration Statement filed on August 16, 2024).
10.4	Amendment to Exclusive Option Agreement, dated January 9, 2021, between Cedars-Sinai Medical Center and Enviro Therapeutics, Inc. (re Sensitization of Solid Tumors) (incorporated by reference to Exhibit 10.4 to the Registration Statement filed on August 16, 2024).
10.5	Exclusive License Agreement, dated June 21, 2021, between Cedars-Sinai Medical Center and Enviro Therapeutics, Inc. (re Compositions and Methods for Treating Diseases and Conditions by Depletion of Mitochondrial or Genomic DNA from Circulation and for Detection of Mitochondrial or Genomic DNA) (incorporated by reference to Exhibit 10.5 to the Registration Statement filed on August 16, 2024).
10.6	Exclusive License Agreement, dated June 2, 2021, between Cedars-Sinai Medical Center and Enviro Therapeutics, Inc. (re Sensitization of Tumors to Therapies Through Endoglin Antagonism) (incorporated by reference to Exhibit 10.6 to the Registration Statement filed on August 16, 2024).
10.7	Exclusive License Agreement, dated August 30, 2019, between Cedars-Sinai Medical Center and Kairos Pharma, Ltd. (as successor to AcTcell Biopharma, Inc.) (re Methods of generating activated T cells for cancer therapy) (incorporated by reference to Exhibit 10.7 to the Registration Statement filed on August 16, 2024).
10.8	Amendment to Exclusive License Agreement, dated June 17, 2021, between Cedars-Sinai Medical Center and Kairos Pharma, Ltd. (re Methods of generating activated T cells for cancer therapy) (incorporated by reference to Exhibit 10.8 to the Registration Statement filed on August 16, 2024).
10.9	Exclusive License Agreement, dated October 1, 2017, between Cedars-Sinai Medical Center and Kairos Pharma, Ltd. (re Methods of use of compounds that bind to RelA of NFkB) (incorporated by reference to Exhibit 10.9 to the Registration Statement filed on August 16, 2024).
10.10	Amendment to Exclusive License Agreement, dated June 17, 2021, between Cedars-Sinai Medical Center and Kairos Pharma, Ltd. (re Methods of use of compounds that bind to RelA of NFkB) (incorporated by reference to Exhibit 10.11 to the Registration Statement filed on August 16, 2024).
10.11	Exclusive License Agreement, dated October 1, 2017, between Cedars-Sinai Medical Center and Kairos Pharma, Ltd. (re Composition and Methods for Treating Fibrosis) (incorporated by reference to Exhibit 10.12 to the Registration Statement filed on August 16, 2024).

10.12	Amendment to Exclusive License Agreement, dated June 17, 2021, between Cedars-Sinai Medical Center and Kairos Pharma, Ltd. (re Composition and Methods for Treating Fibrosis) (incorporated by reference to Exhibit 10.13 to the Registration Statement filed on August 16, 2024).
10.13	Exclusive License Agreement, dated March 12, 2019, between Cedars-Sinai Medical Center and Kairos Pharma, Ltd. (re Composition and Methods for Treating Cancer and Autoimmune Diseases) (incorporated by reference to Exhibit 10.14 to the Registration Statement filed on August 16, 2024).
10.14	Amendment to Exclusive License Agreement, dated June 17, 2021, between Cedars-Sinai Medical Center and Kairos Pharma, Ltd. (re Composition and Methods for Treating Cancer and Autoimmune Diseases) (incorporated by reference to Exhibit 10.15 to the Registration Statement filed on August 16, 2024).
10.15	License and Supply Agreement, dated May 21, 2021, between Tracon Pharmaceuticals, Inc., Enviro Therapeutics, Inc., and Kairos Pharma, Ltd. (incorporated by reference to Exhibit 10.16 to the Registration Statement filed on August 16, 2024)
10.16	First Amendment to Exclusive License Agreement, dated April 18, 2021, between Cedars-Sinai Medical Center and Enviro Therapeutics, Inc. (re Methods for Treating Diseases and Conditions by Depletion of Mitochondrial or Genomic DNA) (incorporated by reference to Exhibit 10.17 to the Registration Statement filed on August 16, 2024).
10.17	Second Amendment to Exclusive License Agreement, dated October 11, 2022, between Cedars-Sinai Medical Center and Enviro Therapeutics, Inc. (re Sensitization of Tumors to Therapies Through Endoglin Antagonism) (incorporated by reference to Exhibit 10.18 to the Registration Statement filed on August 16, 2024).
10.18	Form of Subscription Agreement for 6% Convertible Notes (incorporated by reference to Exhibit 10.20 to the Registration Statement filed on August 16, 2024).
10.19	Form of 6% Convertible Note (incorporated by reference to Exhibit 10.21 to the Registration Statement filed on August 16, 2024).
10.20	Form of Investor Rights and Lock-Up Agreement for 6% Convertible Notes (incorporated by reference to Exhibit 10.22 to the Registration Statement filed on August 16, 2024).
10.21	Kairos Pharma, Ltd. 2023 Equity Incentive Plan (incorporated by reference to Exhibit 10.23 to the Registration Statement filed on August 16, 2024).
10.22	Form of Director Offer Letter (incorporated by reference to Exhibit 10.24 to the Registration Statement filed on August 16, 2024).
10.23	Form of Employment Agreement for John Yu (incorporated by reference to Exhibit 10.25 to the Registration Statement filed on August 16, 2024).
10.24	Form of Employment Agreement with Doug Samuelson (incorporated by reference to Exhibit 10.26 to the Registration Statement filed on August 16, 2024).
10.25	Form of Employment Agreement for Neil Bhowmick (incorporated by reference to Exhibit 10.27 to the Registration Statement filed on August 16, 2024).
10.26	Form of Employment Agreement for Ramachandran Murali (incorporated by reference to Exhibit 10.28 to the Registration Statement filed on August 16, 2024).
10.27	Form of Indemnification Agreement between Kairos Pharma, Ltd. and each of its directors (incorporated by reference to Exhibit 10.29 to the Registration Statement filed on August 16, 2024).
10.28	Conversion Agreement, dated March 7, 2024, between Cedars-Sinai Medical Center, Kairos Pharma, Ltd. and Enviro Therapeutics, Inc. (incorporated by reference to Exhibit 10.30 to the Registration Statement filed on August 16, 2024).
10.29	Second Amendment to the Exclusive License Agreement to Methods and Use of Compounds that Bind to RelA of NF-kB, dated March 7, 2024, between Kairos Pharma Ltd. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.31 to the Registration Statement filed on August 16, 2024).
10.30	Second Amendment to the Exclusive License Agreement to Composition and Methods for Treating Fibrosis with Kairos Pharma Ltd, dated March 7, 2024, between Kairos Pharma, Ltd. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.32 to the Registration Statement filed on August 16, 2024).

10.31	Second Amendment to the Exclusive License Agreement to Compositions and Methods for Treating Cancer and Autoimmune Diseases, dated March 7, 2024, between Kairos Pharma, Ltd. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.33 to the Registration Statement filed on August 16, 2024).
10.32	Third Amendment to Exclusive License to Compositions and Methods for Treating Diseases and Conditions by Depletion of Mitochondrial or Genomic DNA, dated March 7, 2024, between Enviro Therapeutics, Inc. and Cedars-Sinai Medical Center(incorporated by reference to Exhibit 10.34 to the Registration Statement filed on August 16, 2024).
10.33	Third Amendment to the Exclusive License Agreement to Sensitization of Tumors to Therapies Through Endoglin Antoganism, dated March 7, 2024, between Enviro Therapeutics, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.35 to the Registration Statement filed on August 16, 2024).
10.34	Form of Loan Agreement between the Company and Certain Officers (incorporated by reference to Exhibit 10.36 to the Registration Statement filed on August 16, 2024).
10.35	Master Services Agreement, dated August 1, 2024, between Kairos Pharma Limited and Prevail InfoWorks, Inc. (incorporated by reference to Exhibit 10.37 to the Registration Statement filed on August 16, 2024).[(1)]
10.36	Amendment to Loan Agreement, dated August 16, 2024, between the Company and John S. Yu (incorporated by reference to Exhibit 10.38 to the Registration Statement filed on August 16, 2024).
10.37	Amendment to Loan Agreement, dated August 16, 2024, between the Company and Doug Samuelson (incorporated by reference to Exhibit 10.39 to the Registration Statement filed on August 16, 2024).
10.38	Amendment to Loan Agreement, dated August 16, 2024, between the Company and Neil Bhowmick (incorporated by reference to Exhibit 10.40 to the Registration Statement filed on August 16, 2024).
10.39	Bioassay Services Agreement, dated September 20, 2024, between the Company and PreCheck (incorporated by reference to Exhibit 10.1 to the Company's current Report on Form 8-K filed on September 24, 2024).
10.40	Form of Advertising Services Agreement, dated September 23, 2024, between the Company and CEO.CA Technologies, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 27, 2024).
10.41	Form of Advisory & Consulting Agreement, dated September 23, 2024, between the Company and Belair Capital Advisors Inc. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 27, 2024).
10.42	Consulting Agreement, dated October 1, 2024, between Kairos Pharma, Ltd, Cross Current Capital LLC and Alan Masley (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 4, 2024).
10.43	Purchase Agreement, dated November 12, 2024, by and between Kairos Pharma, Ltd. and Helena Global Investment Opportunities I Ltd. (incorporated by reference to Exhibit 10.5 to the Company's Quartey Report on Form 10-Q, filed on November 14, 2024).
10.44	Second Conversion Agreement, dated November 13, 2024, by and between Kairos Pharma, Ltd. and Cedars-Sinai Medical Center. (incorporated by reference to Exhibit 10.6 to the Company's Quartey Report on Form 10-Q, filed on November 14, 2024).
10.45	Third Amendment to Exclusive License Agreement (Cancer Autoimmune), dated November 13, 2024, by and between Kairos Pharma, Ltd. and Cedars-Sinai Medical Center. (incorporated by reference to Exhibit 10.7 to the Company's Quartey Report on Form 10-Q, filed on November 14, 2024).
10.46	Fourth Amendment to Exclusive License Agreement (Depletion of DNA), dated November 13, 2024, by and between Kairos Pharma, Ltd. and Cedars-Sinai Medical Center and Enviro Therapeutics, Inc (incorporated by reference to Exhibit 10.8 to the Company's Quartey Report on Form 10-Q, filed on November 14, 2024).
10.47	Third Amendment to Exclusive License Agreement (Fibrosis), dated November 13, 2024, by and between Kairos Pharma, Ltd. and Cedars-Sinai Medical Center. (incorporated by reference to Exhibit 10.9 to the Company's Quartey Report on Form 10-Q, filed on November 14, 2024).
10.48	Third Amendment to Exclusive License Agreement (RelA of NF-kB), dated November 13, 2024, by and between Kairos Pharma, Ltd. and Cedars-Sinai Medical Center. (incorporated by reference to Exhibit 10.10 to the Company's Quartey Report on Form 10-Q, filed on November 14, 2024).
10.49	Fourth Amendment to Exclusive License Agreement (Sensitization of Solid Tumors), dated November 13, 2024, by and between Enviro Therapeutics Inc. and Cedars-Sinai Medical Center. (incorporated by reference to Exhibit 10.11 to the Company's Quartey Report on Form 10-Q, filed on November 14, 2024).

10.50	Form of the Amendment No.1 to the Employment Agreement by and between Kairos Pharma, Ltd and Doug Samuelson (incorporated by reference to Exhibit 10.12 to the Company's Quartey Report on Form 10-Q, filed on November 14, 2024).
10.51	Form of the Amendment No.1 to the Employment Agreement by and between Kairos Pharma, Ltd and Dr. Ramachandran Murali (incorporated by reference to Exhibit 10.13 to the Company's Quartey Report on Form 10-Q, filed on November 14, 2024).
10.52	Form of the Amendment No.1 to the Employment Agreement by and between Kairos Pharma, Ltd and Dr. Neil Bhowmick (incorporated by reference to Exhibit 10.14 to the Company's Quartey Report on Form 10-Q, filed on November 14, 2024).
10.53	Form of Amendment No. 1 to Employment Agreement by and between Kairos Pharma, Ltd. and John S. Yu (incorporated by reference to Exhibit 10.15 to the Company's Quartey Report on Form 10-Q, filed on November 14, 2024).
10.54	Director Offer Letter, dated December 10, 2024, between Kairos Pharma, Ltd. and Rahul Singhvi (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on December 13, 2024).
10.55	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 14, 2025).
10.56	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed January 14, 2025).
10.57	Form of Lock-up Agreement (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed January 14, 2025).
10.58	Form of Amended and Restated Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed January 17, 2025).
10.59	Placement Agent Agreement, dated January 16, 2025, between Kairos Pharma, Ltd. and Boustead Securities LLC (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed January 17, 2025).
10.60	Services Agreement, dated June 10, 2025, between Kairos Pharma Ltd and the Company and Barretto Pacific Corporation (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K filed June 12, 2025).
10.61	Novation Agreement between Kairos Pharma, Ltd., Enviro Therapeutics, Inc. and Cedars-Sinao Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 7, 2025).
10.62	Novation Agreement between Kairos Pharma Ltd, Enviro Therapeutics, Inc. and Tracon Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed October 7, 2025).
10.63	Form of Restricted Stock Unit Grant Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed October 15, 2025).
10.64	Novation Agreement, dated October 7, 2025 but effective April 17, 2025, between Kairos Pharma, Ltd, Enviro Therapeutics, Inc. and Tracon Pharmaceuticals, Inc. (incorporated by reference to the Current Report on Form 8-K filed October 7, 2025).
10.65	Novation Agreement, dated October 7, 2025, between Kairos Phrma, Ltd., Enviro Therapeutics, Inc. and Tracon Pharmaceuticals, Inc. (incorporated by reference to the Current Report on Form 8-K filed October 7, 2025).
10.66	Form of Amendment No. 83 to Sales Agreement, dated November 12, 2025, between Kairos Pharma Ltd. and Lonza Sales AG (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q filed November 14, 2025).
10.67	Form of Restricted Stock Unit Grant Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed October 15, 2025).
10.68	Term Sheet, dated March 2, 2026, by and between Kairos Pharma, Ltd. and Celyn Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed March 2, 2026).
10.69	Statement of Work 86 to the Lonza Sales Agreement, dated March 27, 2026, between Kairos Pharma, Ltd. and Lonza Sales AG.*
14.1	Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14.1 to the Company's Amendment No. 1 to its Annual Report on Form 10-K/A filed April 29, 2025).
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 to Amendment No. 1 to the Company's Annual Report on Form 10-K/A filed on April 29, 2025).
23.1*	Consent of Weinberg and Company, P.A.
23.2*	Consent of Marcum LLP
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Policy for Recovery of Erroneously Awarded Compensation, adopted March 1, 2024 (incorporated by reference to Exhibit 97.1 to the Company's Amendment No. 1 to its Annual Report on Form 10-K/A filed April 29, 2025)

101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

(1) Certain information contained in this exhibit has been redacted because (i) it is not material and (ii) it is the type of information that the company normally treats as private or confidential.

* Filed herewith.
** 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, the Company has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

KAIROS PHARMA, LTD.

By: */s/ John S. Yu*
John S. Yu
Chief Executive Officer and
Chairman of the Board of Directors
Principal Executive Officer

Date: March 31, 2026

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

Signature	Title	Date
/s/ John S. Yu John S. Yu	Chairman of the board of directors, Chief Executive Officer (principal executive officer)	March 31, 2026
/s/ Doug Samuelson Doug Samuelson	Chief Financial Officer (principal financial and accounting officer)	March 31, 2026
/s/ Hyun W. Bae Hyun W. Bae	Director	March 31, 2026
/s/Hansoo Michael Keyoung Hansoo Michael Keyoung	Director	March 31, 2026
/s/ Rahul Singhvi Rahul Singhvi	Director	March 31, 2026

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Statement of Work 86

To the Agreement between Kairos Pharmaceuticals Ltd and Lonza Sales AG dated 14th February 2008
(novated from Enviro Pharmaceuticals Inc. pursuant to a Novation Agreement dated 8th November 2025)

Number	86	
Product Code	TRC105 / ENV105	
Description of the proposed change:	Amend the existing Stage 7 under the Agreement. **Stage 7. cGMP Batch Campaign 1,000L (Slough)**	
Price Agreed	See Schedule 3	
Kairos Pharmaceuticals LTD.	Name: John S. Yu Signature:	Date: 27 - March - 2026
Lonza Sales AG	Name: Altekrueger Cordula Signature: DocuSigned by Altekrueger Cordula	Date: 19-Mar-2026 | 09:08:05 CET
Lonza Sales AG	Name: Marc Therrode Signature: DocuSigned by Marc Therrode	Date: 19-Mar-2026 | 08:58:49 CET

Docusign Envelope ID: 6BEE5A1F-AC60-4C20-8347-052FC8169646

Stage 7. cGMP Batch Campaign 1,000L (Slough)

7.1. Objectives

- To manufacture Product in a stirred tank single-use bioreactor in accordance with the principles of cGMP based upon procedures established in previous Stages. Product to be produced as one (1) Batch.

7.2. Activities

- After receiving adequate testing data for virus, sterility, viability and mycoplasmas on the cell bank designated for manufacturing, recover cells from one (1) vial of the cell bank and expand culture sufficient to inoculate the fermentation system.
- Perform a stirred tank single use fermentation.
- Clarify fermentation contents by filtration.
- Purify filtrate.
- Sample for subsequent studies, as appropriate (eg, virus reduction studies).
- Take in process samples according to the sampling plan.
- Test Product against the cGMP Product Certificate of Analysis.
- Review Batch documentation.
- Provide the Customer with QA audited consolidated data packs for fermentation and purification.
- Disposition Product and issue Certificate of Analysis, as appropriate.

7.3. Deliverables

- Purified bulk Drug Substance
- Consolidated Batch record
- Typically, the consolidated Batch record includes:
    - Certificate of Analysis,
    - Certificate of Analysis attachments,
    - Certificate of Compliance,
    - Copies of Batch documentation used in the execution of the Manufacturing Process; inoculum, fermentation, purification, and final bulk fill.

7.4. Assumptions

- The Manufacturing Process will fit the current Facility operating conditions, durations and equipment. Should there be a requirement for additional equipment, processing time and/or other non-standard operability criteria this will be agreed by Lonza and the Customer.
- The duration in the production bioreactor will be up to a maximum of fifteen (15) days from inoculation up to and including harvest and all feeds can be applied through two (2) inlets.
- Pre-packed columns (PPC) will be used as standard for GMP manufacture. If this is not the case, alternative options are subject to discussion with Price and Terms to be agreed between Lonza and the Customer.
- The duration of the purification Process will be up to ten (10) days in purification (plus one (1) day in the post virus reduction filtration suite and one (1) day for bulk fill), certain volume, and titre restrictions apply.
- Shelf life will be set for all cGMP Batches. This will be assigned using Product-specific stability data, or Lonza generic shelf life will be applied, which requires assessment against pre-requisites. If no shelf life can be set, a minimum six (6) month shelf life will be assigned. Shelf life will be applied from the bulk fill.
- Customer may request Lonza to cryopreserve an end of production cell bank (EPC) and additional day of harvest samples from the fermentation for testing. Preparation and testing can be arranged and will be on additional terms to be agreed.
- The purification process comprises up to three (3) chromatography steps.
- Bulk fill is into bags as standard and certain volume, and titre restrictions apply.

- Extensive sampling may result in a lower than expected yield.
- Prior to subsequent batches, requirements (if any) for Manufacturing Process modifications may be reviewed. Any such Manufacturing Process modifications are subject to agreement between Lonza and Customer and may be subject to an amendment to this Agreement.
- Affinity Resins from the Manufacturing Process will be stored at Lonza until the manufacturer's expiration or the Lonza expiry date has been reached (whichever is sooner) as per Lonza policy. After this time, these Resins will be discarded or shipped to the Customer.
- Samples taken during manufacture and not used in subsequent Stages will be stored until the completion of this Stage at Lonza. After this time, these samples will be discarded or shipped to the Customer.

7.5. Estimated Duration

- Eighteen (18) week(s)

Schedule 3

Price and Terms of Payment

Price

In consideration for Lonza performing the Services as detailed in Schedule 2 Customer shall pay Lonza as follows:

Manufacturing

Stage	Name	Number of Batches	Price per Batch
7	**cGMP Batch Campaign 1,000L (Slough)**	1	GBP 1,300,000

Remarks:

- *Pricing assumes Lonza's standard Manufacturing Process durations apply. Additional days in downstream processing due to the intermediate UFDF requirement are charged at an additional cost as listed in the table below*

Stage	Name	Price for two (2) additional facility days
7	**cGMP Batch Campaign 1,000L (Slough)** – Optional additional days in facility	GBP 106,711.00

Remarks:

- *Pricing assumes previously performed Manufacturing Process was selected requiring two (2) additional days in facility. An additional two (2) days in downstream processing due to the intermediate UFDF requirement (total DSP = maximum of nine (9) days) are charged at an additional cost. To be determined and confirmed by customer prior to commencement of Stage 7.*

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Raw Materials and/or Externals Estimates

Name	Unit/Amount	Indicative Cost
Raw & Consumables Estimate 1000L cGMP Batch (Slough) (excludes capture resin)	Per Batch	GBP 440,000
Resin & Membranes Estimate (20L capture resin) 1000L cGMP Batch (Slough)	Batch(es)	GBP 410,000

Remarks:

- *All costs are estimates and are subject to re-evaluation as the project progresses.*
- *Costs from External Laboratories and other third party contractors will be passed through to Kairos Pharmaceuticals with a 10% management fee for sample preparation, results processing and review.*
- *Raw Materials, consumables / disposables will be charged at cost (purchase price) plus a 15% Raw Materials Fee.*
- *It is assumed that pre-packed columns will be used as standard for GMP manufacture.*
- *Resin amount assumes a 10% overage for column packing, if required.*
- *The frequency of Resin and membrane exchange will be determined based on the validated Resin lifetime as well as quality operational requirements.*
- *Resins will be charged at cost (purchase price) plus a 15% handling fee.*
- *All Prices are exclusive of Customer specific Raw Materials, examples of which include (but not limited to): HPLC columns, antibody reagents and other assay reagents / kits. These will be notified to the Customer by Lonza in advance of purchase or use and invoiced together with Handling Fees.*
- *The estimated raw material and resin costs are based on data from historical cGMP batches executed at the target site and scale. While these estimates provide a useful benchmark, they may not fully reflect the specific requirements of your process. Final costs will be updated following the development of a Product-specific Bill of Materials and completion of at-scale process modelling.*

Payment and Delivery Terms

- *50% on start of each Service and 50% on completion of each Service.*
- *Specific subsets of Service may deviate regarding the payment schedule (e.g. stability studies, regulatory services, others).*
- *Payment Net 30 days after receipt of invoice*
- *External costs will be invoiced periodically or when the specific activity is complete.*

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-292686), Form S-1 (File Nos. 333-286662 and 333-284569) and Form S-8 (File No. 333-282391), of our report dated March 31, 2026, (which report contains an explanatory paragraph describing conditions that raise substantial doubt about Kairos Pharma, Ltd.'s ability to continue as a going concern) relating to the financial statements of Kairos Pharma, Ltd. as of December 31, 2025 and for the year then ended, included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Weinberg & Company, P.A.
Los Angeles, California
March 31, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement on Forms S-1 (Nos. 333-284569 and 333-286662), Form S-3 (No. 333-292686) and Form S-8 (No. 333-282391) of our report dated April 15, 2025, with respect to the consolidated financial statements of Kairos Pharma, Ltd. included in this Annual Report on Form 10-K for the year ended December 31, 2024.

/s/ Marcum llp

Los Angeles, CA
March 31, 2026

Exhibit 31.1

CERTIFICATION

I, John S. Yu, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of Kairos Pharma, Ltd. (the "registrant");

2. Based on my knowledge, this Annual 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 Annual Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Annual 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 Annual Report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this Annual Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Annual Report based on such evaluation; and

d. Disclosed in this Annual Report any change in the registrant's internal control over financial reporting that occurred during the registrant's fourth fiscal quarter 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 31, 2026

/s/ John S. Yu
John S. Yu
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT

I, Douglas Samuelson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Kairos Pharma, Ltd.:

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(r) and 15d-15(r) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2026

By: */s/ Douglas Samuelson*
Douglas Samuelson
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

Exhibit 32.1

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

In connection with the Annual Report of Kairos Pharma, Ltd. (the "Company") on Form 10-K for the fiscal year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John S. Yu, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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 31, 2026

/s/ John S. Yu
John S. Yu
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Annual Report of Kairos Pharma, Ltd. (the "Company") on Form 10-K for the fiscal year ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Doug Samuelson, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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 31, 2026

/s/ Doug Samuelson
Doug Samuelson
Chief Financial Officer
(Principal Financial Officer)