Filed Pursuant to Rule 424(b)(4)
File No. 333-274805

1,550,000 Shares

Kairos Pharma, Ltd.

Common Stock

This is a firm commitment initial public offering of shares of common stock, par value $0.001 per share, of Kairos Pharma, Ltd. We are offering 1,550,000 shares of our common stock at an initial public offering price of $4.00 per share.

Prior to this offering, there has been no public market for our common stock. Our common stock has been approved for listing on the NYSE American LLC, or NYSE American, under the symbol "KAPA."

We are an "emerging growth company" as defined under the federal securities laws and, as such, will be subject to reduced public company reporting requirements. See "Prospectus Summary — Implications of Being an Emerging Growth Company" for additional information.

Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors beginning on page 10 of this prospectus prior to making a decision to invest in our common stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	*Total*
Initial public offering price	$ 4.00	**$** 6,200,000
Underwriting discounts and commissions(1)	**$** 0.28	**$** 434,000
Proceeds to us, before expenses	**$** 3.72	**$** 5,766,000

(1) We have agreed to pay the underwriters a cash fee equal to 7.0% of the aggregate gross proceeds from the sale of the common stock. The underwriters will also be entitled to warrants to purchase up to 7.0% of the aggregate number of shares of our common stock sold in this offering and a 1% non-accountable expense allowance, which amount is not included above. We have also agreed to reimburse the underwriters for certain expenses incurred by them. See "Underwriting" beginning on page 130 of this prospectus for more information about the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 45 days to purchase up to an additional 232,500 shares of common stock from us at the initial public offering price less underwriting discounts and commissions to cover over-allotments, if any. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $499,100, and the total proceeds to us, before expenses, will be $6,630,900.

Delivery of the shares is expected to be made on or about September 17, 2024.

Boustead Securities, LLC **EF Hutton LLC**

Sutter Securities, Inc.

Prospectus dated September 16, 2024

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ABOUT THIS PROSPECTUS

Neither we nor the underwriters have authorized anyone to provide you any information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations, and prospects may have changed since that date.

For investors outside of the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should carefully read this entire prospectus, including the information under the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements," and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless otherwise necessary or appropriate in the context, references in this prospectus 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.

Our Company

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 transform the way cancer is treated. We have leveraged molecular insights to develop a new class of novel drugs that we expect will target drug resistance and checkpoints of immune suppression. "Checkpoints" refer to molecules on certain immune cells that need to be activated (or inactivated) to start an immune response. Our portfolio of seven drug candidates offers diversification and mitigates the overall exposure to many of the inherent risks of drug development. Our key patents are licensed from Cedars-Sinai Medical Center, the largest academic medical center in the Western United States, and Tracon Pharmaceuticals, Inc., a clinical stage public biopharmaceutical company based in California. The science underlying the patents was developed at Cedars-Sinai Medical Center and was licensed to us from this institution.

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. 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 that is designed to transform a patient's T cells into killer activated T cells against cancerous stem cells. These activated T cells are induced to target several antigen targets on glioblastoma cancer stem cells, the initiators and propagators of glioblastoma tumors.

In June 2021, Kairos acquired Enviro Therapeutics, Inc., a California corporation ("Enviro"), through a share exchange. Enviro's shareholders exchanged 100% of the outstanding shares of Enviro for 6,000,000 shares of newly issued restricted shares of common stock of Kairos. After the closing, Enviro became a wholly owned subsidiary of Kairos. The acquisition allowed us to incorporate into our company Enviro's 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 the prostate and lung cancer markets and that we believe can help address cancer progression in those cancers that develop resistance to standard therapies.

Our drug candidate portfolio currently consists of a pipeline of seven drug candidates, including KROS drugs, which are immunotherapeutics, and ENV antibodies, which are designed to reverse drug resistance that often results as a consequence of the use of cancer therapeutics. Our pipeline is summarized below:

- Five pre-clinical or clinical-trial stage drug candidates developed by us and designed to target immune response, including KROS 101, 102, 201, 301, and 401, which are designed to reverse immunosuppression of T cells that is caused by cancer.
    - KROS 101 and 102 are small molecules that are agonist and antagonist for the GITR (glucocorticoid induced TNF-like receptor) ligand, which respectively promote and inhibit T cell growth and function. GITR is a checkpoint central to control the numbers of T cells of the immune system. These molecules are in the preclinical stage and are being developed for clinical trials.
    - KROS 201 is an autologous T cell therapy targeting cancer stem cells of glioblastoma. This therapy has received an IND from the FDA for clinical trial and is undergoing preparation for a Phase 1 clinical trial for patients with recurrent glioblastoma.
    - KROS 301 is a small molecule that targets the NF-κβ pathway, a cancer growth and immune suppressive molecule in triple negative breast cancer. This molecule is in preclinical testing.
    - KROS 401 is a cyclic peptide which inhibits the IL-4 and IL-13 (cytokines that play a critical role in the suppression of T cells by macrophages at the site of the tumor) receptor and is designed to reverse the immunosuppression induced by macrophages in the tumor microenvironment.
- Two therapeutic agents developed by our Enviro subsidiary and designed to increase anti-tumor response in conjunction with cancer therapies by addressing resistance to these agents.
    - ENV 105 is an antibody that targets CD105 / Endoglin which is expressed in tumor cells and surrounding cells as the tumor becomes resistant to therapeutics in prostate cancer and lung cancer. This therapy is being tested in a randomized multicenter Phase 2 trial for prostate cancer and a Phase 1 trial in lung cancer, both of which began enrolling patients in September 2023. ENV 105 has received an IND from the FDA.
    - ENV 205 is an antibody that targets mitochondrial DNA which is elevated as patients become resistant to chemotherapies. This therapy is in preclinical testing.

As of the date of this prospectus, our product candidates have not been approved as safe or effective by the FDA or any other comparable foreign regulator.

Our In-Development Products and Pipeline

We develop a broad portfolio of novel and transformative drug therapies to treat cancer. Our current portfolio consists of seven drug therapies consisting of therapeutic agents ENV 105 and 205 to counter drug resistance and cancer immunotherapeutic KROS 101, 102, 201, 301, and 401, as described above.

Our ENV 105 biologic drug seeks to address unmet medical needs in large markets of prostate and lung cancers. ENV 105 targets endoglin and reverses 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 in 2018 with an IND from the FDA. 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. The trial enrolled 11 patients of which nine were evaluable. This investigator-initiated trial closed to accrual prior to its planned enrollment of 40 patients due to limitations of the drug supply from the manufacturer. The drug supply has since been expanded and obtained by Kairos Pharma. 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 who 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 (performed by the National Cancer Institute). However, two agents that apparently have no clinical effect, when combined result in halting tumor progression in the majority of patients. The finding is supported by numerous publications reporting on studies that demonstrated hormone therapy resistance develops through the induction of CD105, the target of ENV105. In addition, all of the patients participating in the trial were not only resistant to the two hormone therapy agents but also resistant to at least one other intervention after surgical or radiation progression. Some patients failed to respond to as many as five other drugs. The responders to the combination therapy were patients who, at that point, had exceedingly few other options for survival. While ENV105 has neither been declared safe or effective by the FDA, the efficacy and safety data from the clinical trial are available for review at the clinicaltrials.gov website: https://www.clinicaltrials.gov/study/NCT03418324?cond=PROSTATE%20CANCER&intr=TRC105&rank=1&tab=results.

A three-gene panel was identified to serve as a companion biomarker for patient selection. Depending on the level of expression of three genes, this testing identified potential drug responders prior to therapy. Our Enviro subsidiary will aim to co-develop companion biomarkers with all drugs in its portfolio, enabling identification of potential drug responders prior to therapy. Separate approvals will be required for the development and approval of companion diagnostics. These approvals may be delayed or not issued by the FDA. As of the date of this prospectus, our companion diagnostics are in development and have not been approved by the FDA. In addition, there is no guarantee that these companion diagnostics will be approved by the FDA or comparable foreign regulatory agencies. The ENV 105 Phase 2 multi-center trial in prostate cancer will be randomized with and without ENV 105 in patients treated with apalutamide (Janssen). The Phase 1 trial in lung cancer will be conducted with Tagrisso (AstraZeneca).

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. Although as of the date of this prospectus, ENV 205 has not been approved by the FDA or any other comparable foreign regulator. However, we are not aware of any other biologic that is further along than ENV 205 in the development process that targets prostate cancers that have become otherwise resistant to chemotherapy. ENV 205 is an antibody that 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 in animal models that received ENV 205 along with chemotherapy with the aim of reducing its toxic side effects.

As of the date of this prospectus, all of our operations have been conducted virtually as we attempt to be efficient with our capital resources. Going forward, we intend to leverage our history with premier academic medical centers to efficiently enroll and execute clinical trials.

We have filed an Investigational New Drug, or IND, application with the FDA that has become effective for **ENV 105**. As a result, in September 2023 we began enrolling patients for a Phase 1 trial for non-small cell lung cancer and also began enrolling patients in a randomized, multi-institutional Phase 2 trial for prostate cancer. The mechanism of action for **ENV 105** addresses the resistance mechanism of tumor dormancy. This is 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. 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 that the co-administration of **ENV 105** specifically targets this mechanism of resistance.

Through the Enviro 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, which is a wasting syndrome that leads to loss of skeletal muscle and fat that occurs in up to 30% of people with advanced cancer according to the National Cancer Institute.

Our Strategy

Our goal is to unlock the power of the immune system on the two most pervasive problems in cancer treatment: resistance to therapy and immune suppression by cancer. We believe this road will lead to major improvement in the quality of life of cancer patients and will transform patient outcomes. Our strategy consists of the following:

- Creating 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 caused by cancer.
- Leverage our academic research and clinical connections with our industry collaborations.
- Advance our lead resistance candidate, ENV105, to complete a randomized multi-institutional Phase 2 trial in prostate cancer (enrollment began in September 2023).
- Complete enrollment in a Phase 1 trial of ENV105 in patients with non-small lung cancer on Tagrisso (enrollment commenced in September 2023).
- 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.

Our Key Team Leaders

Our company is led by Dr. John S. Yu, our Chairman and Chief Executive Officer, Dr. Neil Bhowmick, our Chief Scientific Officer, and Dr. Ramachandran Murali, our Vice President of Research and Development. Dr. Yu is a Professor in the Department of Neurosurgery and Director of Surgical Neuro-Oncology at Cedars-Sinai Medical Center in Los Angeles, California. Dr. Bhowmick is a Professor of the Department of Medicine and a Research Scientist in Cancer Biology at Cedars-Sinai Medical Center. Dr. Murali is a Professor of Biomedical Sciences and Director of the Molecular Therapeutics Core at Cedars-Sinai Medical Center. The group of founding scientists generating our initial drug candidates have combined their pioneering contributions in structural, biology, immunology and cancer therapy to bring what we believe are life changing therapeutics to unmet medical needs.

License Agreements

License Agreements with Cedars-Sinai

On June 2, 2021, Enviro entered into two Exclusive License Agreements with Cedars-Sinai, which granted Enviro exclusive licensing rights (including the right to sublicense) with respect to certain patent rights owned by Cedars-Sinai, 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, together 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.

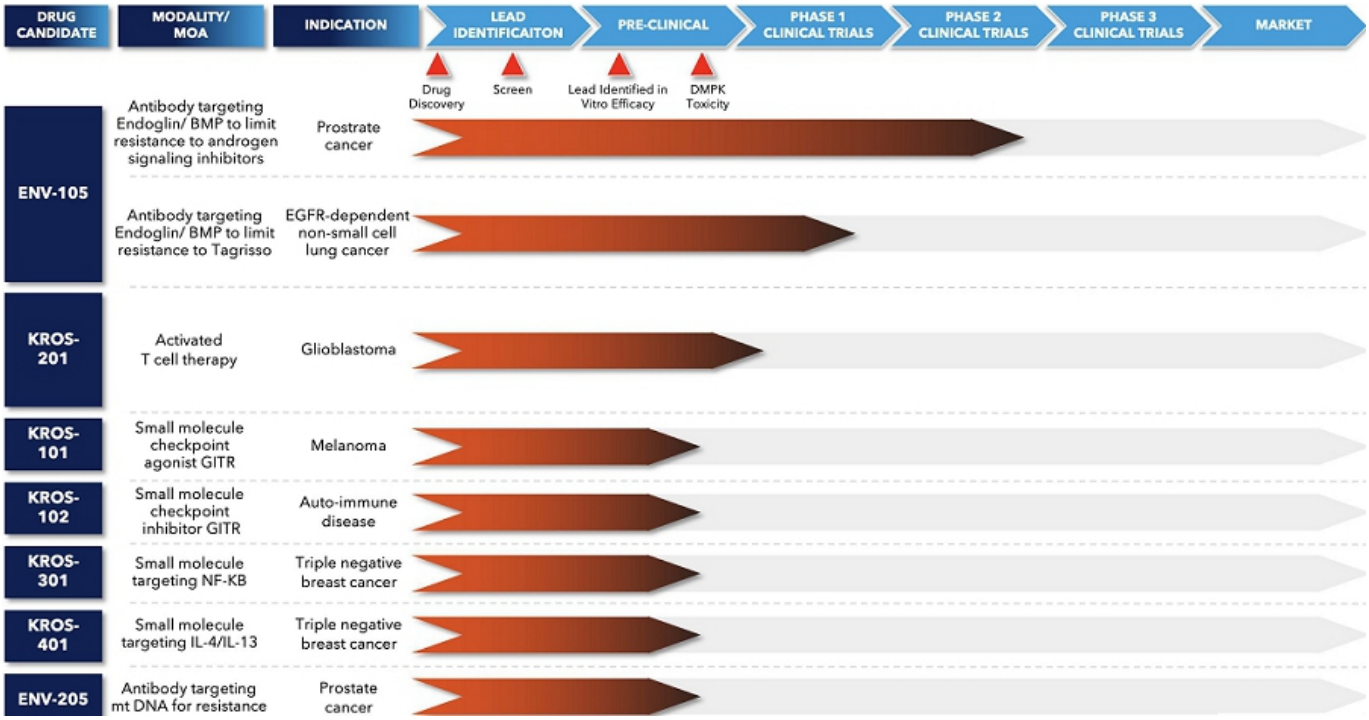
License Agreement with Tracon Pharmaceutical, Inc.

On May 21, 2021, Enviro entered into a License Agreement with Tracon Pharmaceutical, Inc. ("Tracon"). Pursuant to the Tracon License Agreement, Tracon granted 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" (all as defined or described in the Tracon License Agreement).

All of our patent rights are in-licensed from third parties under license agreements that require meeting certain milestones for continuation of those agreements.

Our Development Programs

Our drug development programs for **KROS 101**, **102**, **201**, **301**, and **401** as well as therapeutic agents **ENV105** and **ENV 205** are summarized in the following table.



Pre-IPO Bridge Financing

In June and September 2022, we completed a $450,000 convertible note offering and a $225,000 convertible note offering, respectively, to certain accredited investors. The notes automatically converted upon the effectiveness of this offering into shares of common stock (the "Conversion Shares") at a conversion price equal to 60% of the initial public offering price. The convertible note offerings were completed pursuant to an exemption from registration under Rule 506(b) of the Securities Act of 1933, as amended (the "Securities Act"). Boustead Securities, LLC acted as placement agent in each of the June and September 2022 private placements and received $86,893 and $19,315 cash compensation, respectively, and five-year warrants to purchase shares of common stock equal to 7.0% of the number of the Conversion Shares at an exercise price equal to the conversion price.

Recent Grants Awarded through the National Institutes of Health

On May 21, 2024, we learned that the National Cancer Institute / National Institutes of Health ("NIH") 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.

Summary of Risk Factors

Our business is subject to a number of risks and uncertainties of which you should be aware before making an investment decision. You should consider all of the information set forth in this prospectus and, in particular, the specific factors set forth under "Risk Factors" in deciding whether to invest in our securities. These risks include, without limitation, the following:

- 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.
- 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 face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than we do.
- We are relying exclusively on the skills and expertise of our management team in conducting our business, not all of the management team will devote all of their time to managing the Company, and we currently have no full-time employees, which may impede our ability to carry on our business.
- 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 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 or our exclusive licensing rights may be terminated.
- 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.
- 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.
- 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.
- 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 not realize the full commercial potential of our product candidates.
- 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.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed.
- 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.
- If you purchase common stock in this offering, you will suffer immediate dilution of your investment.
- The trading price of our common stock may be volatile, and you could lose all or part of your investment.

Corporate History and Information

Kairos Pharma, Ltd. was originally incorporated on June 17, 2013 under the laws of the State of California as NanoGB13, Inc. We changed our 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 Secretary of State of the State of Delaware a certificate of conversion from a non-Delaware corporation to a Delaware corporation pursuant to the Delaware General Corporation Law. In addition, on May 10, 2023, we also filed a certificate of incorporation with the Secretary of State of the State of Delaware and became 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 (the "Reverse Stock Split"). After the Reverse Stock Split, effective as of May 10, 2023, there were 10,334,357 shares of our common stock outstanding.

We presently conduct all of our operations virtually when possible. Our registered corporate address is 2355 Westwood Blvd., #139, Los Angeles, California 90064 and our corporate website is https://kairospharma.com. The information contained in, or accessible from, our website or any other website does not constitute a part of this prospectus.

Implications of Being an Emerging Growth Company and Smaller Reporting Company

We are an "emerging growth company" and a "as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act. We may take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm under Section 404 of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments. We may take advantage of these exemptions for up to five years or until we are no longer an "emerging growth company," whichever is earlier. We will cease to be an emerging growth company prior to the end of such five-year period if certain earlier events occur, including if (i) we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or Exchange Act, (ii) our annual gross revenues exceed $1.07 billion, or (iii) we issue more than $1.0 billion of non-convertible debt in any three-year period. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period to comply with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of accounting standards that have different effective dates for public and private companies 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 a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may continue to be a smaller reporting company after this offering if either (i) the market value of our shares held by non-affiliates is less than $250 million as measured on the last business day of our second fiscal quarter or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million as measured on the last business day of our second fiscal quarter. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and have reduced disclosure obligations regarding executive compensation. Further, if we are a smaller reporting company with less than $100 million in annual revenue, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

Market, Industry, and Other Data

We obtained the industry, market, and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry, and general publications and surveys, governmental agencies, and publicly available information in addition to research, surveys, and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market, and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

The Offering

Common stock offered by us	1,550,000 shares of common stock
Underwriters' over-allotment option	We have granted the underwriters an option for a period of 45 days to purchase up to an additional 232,500 shares of our common stock from us at the initial public offering price less underwriting discounts and commissions to cover over-allotments, if any.
Common stock outstanding immediately before this offering	10,562,640 shares of common stock
Common stock outstanding immediately after this offering	12,841,937 shares (or 13,074,437 shares if the underwriters' over-allotment option to purchase additional shares from us is exercised in full).
Use of proceeds	We estimate that we will receive net proceeds from this offering of approximately $5.6 million (or approximately $6.4 million if the underwriters' option to purchase additional shares of our common stock is exercised in full) based on the initial public offering price of $4.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to fund Phase 1 and Phase 2 clinical trials of our product candidates, including ENV 105 and preclinical product candidates including KROS 101, potential acquisition or in-licensing activities, and working capital and general corporate purposes. The funds are expected to be used as follows: ● approximately $1.0 million, or 18% of the net proceeds, will be used to fund the clinical development of our lead product candidate in Phase 1 and Phase 2 trials of ENV 105; ● approximately $0.7 million will be used to pay outstanding accounts payable; and ● any remaining proceeds will be used for working capital and general corporate purposes. The use of proceeds could differ from the estimates set forth above in the event enrollment in our clinical trials is greater than expected in the first 12 months. If that happens, we may need to use additional proceeds to fund our clinical trials. See the section titled "Use of Proceeds" for additional information.
Risk factors	See the section titled "Risk Factors" and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
NYSE American trading symbol	"KAPA"

The 12,841,937 shares of our common stock to be issued and outstanding immediately after this offering is based on 10,562,640 shares of common stock issued and outstanding as of September 16, 2024 and gives effect to the automatic conversion of all convertible notes payable, notes payable – officers, and the related accrued interest into 369,248 shares of our common stock upon the effectiveness of this offering, 1,664 shares of our common stock upon the conversion of amounts due to related parties, 45,885 shares of our common stock upon the conversion of amounts due to one of our officers for past services, and 312,500 shares of our common stock upon the conversion of certain accounts payable upon the effectiveness of this offering (see "Our Company Pre-IPO Bridge Financing" above), and excludes:

- 150,000 shares of our common stock issuable upon the exercise of outstanding common stock purchase warrants with a weighted-average exercise price of $4.17 per share; and
- 1,650,000 shares of common stock reserved for future issuance under our equity incentive plan.

Unless otherwise indicated, this prospectus assumes or gives effect to:

- no exercise of the outstanding warrants described above;
- no exercise by the underwriters of their option to purchase additional shares of common stock from us in this offering;
- an initial public offering price of $4.00 per shares; and
- no exercise of the warrants expected to be issued to the underwriters as compensation for this offering.

Summary Financial Data

The following tables set forth our summary financial data for the periods and as of the dates indicated. The following summary statements of operations for the years ended December 31, 2022 and 2023 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. We derived our statements of operations data for the six months ended June 30, 2023 and 2024, and our summary balance sheet data as of June 30, 2024, from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. The unaudited condensed consolidated financial statements were prepared on a basis consistent with our audited consolidated financial statements and include, in management's opinion, all adjustments, consisting only of normal recurring adjustments that we consider necessary for a fair presentation of the financial information set forth in those statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future, and the results of operations for the six months ended June 30, 2024 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2024, or any other period. You should read the following summary financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes included elsewhere in this prospectus. The summary financial data included in this section are not intended to replace the financial statements and are qualified in their entirety by our financial statements and the related notes included elsewhere in this prospectus.

	Years Ended December 31,		Six Months Ended June 30,	
	2022	2023	2023	2024
	(In thousands, except share and per share amounts)			
			(Unaudited)	
Statements of Operations Data				
Operating expenses:				
Research and development	$ 87	$ 82	$ 42	$ 228
General and administrative	484	1,632	296	286
Total operating expenses	571	1,714	338	514
Loss from operations	(571)	(1,714)	(338)	(514)
Other expenses:				
Interest expense	(51)	(42)	(24)	(23)
Debt discount amortization	(408)	(56)	(20)	(39)
Financing costs	(20)	-	-	-
Total other expenses	(479)	(98)	(44)	(62)
Net loss	$ (1,050)	$ (1,812)	$ (382)	$ (576)
Basic and diluted loss per share (1)	$ (0.10)	$ (0.17)	$ (0.04)	$ (0.05)
Weighted-average common shares outstanding - basic and diluted (1)	10,236,764	10,382,515	10,334,357	10,562,640
Pro forma net loss per share, basic and diluted (unaudited) (1)	$ (0.10)	$ (0.16)	$ (0.03)	$ (0.05)
Pro forma weighted-average common shares outstanding (unaudited) (1)	10,839,452	11,031,054	10,962,699	11,215,807

(1) See Note 2 to our financial statements included elsewhere in this prospectus for a description of how we compute basic and diluted net loss per common share and the number of shares used in computing these amounts.

	As of June 30, 2024		
	Actual	Pro Forma (1)	Pro Forma As Adjusted (2)
	(Unaudited)	(Unaudited)	(Unaudited)
Balance Sheet Data (in thousands):			
Cash	$ 21	$ 21	$ 5,621
Working capital (3)	(2,947)	(1,855)	3,745
Total assets	1,030	1,030	6,630
Notes payable - officers	102	-	-
Convertible notes payable, net of debt discount of $66	677	-	-
Total liabilities	3,684	1,915	1,915
Additional paid-in capital	4,123	5,958	11,556
Accumulated deficit	(6,788)	(6,854)	(6,854)
Total shareholders' equity (deficit)	(2,654)	(885)	4,715

(1) The pro forma column in the balance sheet data gives effect to (i) the automatic conversion of all convertible notes payable, notes payable – officers and the related accrued interest into 369,248 shares of common stock, (ii) the issuance of 312,500 shares of common stock upon the conversion of certain accounts payable, upon the effectiveness of this offering, (iii) the issuance of 45,885 shares of common stock upon the conversion of amounts due to an officer, and (iv) the issuance of 1,664 shares of common stock upon the conversion of amounts due to related parties.

(2) The pro forma, as adjusted column in the balance sheet data gives effect to (i) the items described in footnote (1) above and (ii) the issuance and sale of 1,550,000 shares of our common stock in this offering at the initial public offering price of $4.00 per share after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Working capital is defined as current assets less current liabilities. See our financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before you invest in our common stock, you should carefully consider the risks described below together with all of the other information contained in this prospectus, including our audited financial statements and unaudited condensed financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this prospectus. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, and growth prospects. Unless otherwise indicated, references in these risk factors to our business being harmed will include harm to our business, reputation, financial condition, results of operations, and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

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 believe that the net proceeds from this offering will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. However, 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, including purchasers of shares of our common stock in this offering, 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.

The report of our independent registered public accounting firm included a "going concern" explanatory paragraph.

The report of our independent registered public accounting firm on our financial statements as of and for the years ended December 31, 2022 and 2023 included an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern. If we are unable to raise additional capital as and when needed, our business, financial condition and results of operations will be materially and adversely affected, and we may be forced to delay our development efforts, limit our activities and reduce research and development costs. If we are unable to continue as a going concern, we may have to liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The inclusion of a going concern explanatory paragraph by our independent registered public accounting firm, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into licensing and collaboration arrangements or other contractual relationships with third parties and otherwise execute our development strategy.

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, recent changes to leadership, enhanced focus on countermeasures related to the COVID-19 pandemic, and the 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 the COVID-19 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 "— 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, including as a result of the COVID-19 pandemic, 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 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 the outbreak of the coronavirus (COVID-19) or from another 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. For example, as a result of measures imposed by the governments in regions affected by COVID-19 businesses and schools have been suspended due to quarantines or "stay at home" orders intended to contain this outbreak. The spread of COVID-19 from China to other countries has resulted in the Director General of the World Health Organization declaring the outbreak of COVID-19 as a Public Health Emergency of International Concern (PHEIC), based on the advice of the Emergency Committee under the International Health Regulations (2005). In March 2020, and subsequently, various international travel restrictions were imposed and modified between the US and foreign countries and such restrictions may continue, be reimposed, or be expanded or otherwise further modified for the foreseeable future. COVID-19 continues to spread globally, including with the advent of the new "delta" and "omicron" variants in 2021 and 2022. The COVID-19 outbreak has impacted international stock markets, which continue to reflect the uncertainty associated with the slow-down in global economies and the reduced levels of international travel experienced since the beginning of January 2020. We continue to assess our business plans and the impact COVID-19 may have on our ability to advance the development of our drug candidates, including delays in starting or completing clinical trials, or to raise financing to support the development of our drug candidates, but no assurances can be given that this analysis will enable us to avoid part or all of any impact from the spread of COVID-19 or its consequences, including downturns in business sentiment generally or in our sector in particular.

The spread of an infectious disease, including COVID-19, may also 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.

Separately, in response to the global COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. 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 the COVID 19 pandemic.

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, in conjunction with our wholly-owned subsidiary Enviro Therapeutics, to co-develop companion biomarkers with all drugs in its 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 prospectus 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 have no full-time employees, 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. Although upon the effectiveness of our registration statement, our Chief Financial Officer now serves on a full-time basis, we presently 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, we may not have sufficient devoted time and effort 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 September 16, 2024, we had three part-time employees, including our Chief Executive officer, and our Chief Financial Officer was a part-time contractor. Upon the effectiveness of our registration statement, our Chief Financial Officer began serving on a full-time basis. 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 employment with us at any time and will continue to be able to do so after the completion of this offering. 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.

Our business could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic.

Our business could be adversely affected by health epidemics, including the COVID-19 pandemic, in regions where we or third parties on which we rely have manufacturing facilities, concentrations of potential clinical trial sites or other business operations. We continue to evaluate our protocols and practices as the global response to the COVID-19 pandemic continues to evolve. There can be no assurance that we will be able to avoid part or all of any impact from the spread of COVID-19 or its consequences.

In addition, our current preclinical and nonclinical studies and current and future clinical trial plans may be affected by the COVID-19 pandemic. Site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic, which may delay enrollment in our future global clinical trials, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Further, some of our suppliers may experience disruption to their respective supply chain due to the effects of health epidemics, including the COVID-19 pandemic, which could delay, prevent, or impair our development or commercialization efforts.

The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. Several measures are currently being implemented by the United States and other governments to address the current COVID-19 pandemic and its economic impacts. At this time, it is impossible to predict the impact of these measures and whether or not they will have unforeseen negative consequences for our business. We do not yet know the full extent of potential delays or impacts on our business, our planned preclinical studies or clinical trials, healthcare systems or the global economy as a whole; nor do we know when and how such regulations may be eased. The foregoing and other continued disruptions to our business as a result of COVID-19 could result in an adverse effect on our business, results of operations, financial condition and cash flows. Furthermore, the COVID-19 pandemic could heighten the risks in certain of the other risk factors described herein.

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.

Prior to the completion of this offering, we have been a private company with limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. 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; these third-party licensors also own equity with certain anti-dilution and participation rights.

Our agreements with Cedars-Sinai Medical Center and Tracon Pharmaceuticals, Inc. 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.

Pursuant to the Enviro-Cedars license agreements, Enviro would also issue to Cedars shares of Enviro's common stock equal to, in the aggregate between the two Enviro-Cedars license agreements, 2.0% of Enviro's outstanding equity on a fully diluted basis. Cedars also has certain anti-dilution protections, whereby Enviro shall issue to Cedars, without consideration, additional shares necessary to ensure that Cedars maintains at least 2.0% of the equity issued and outstanding on a fully diluted basis until the earlier of (i) Enviro's initial public offering or (ii) Enviro having raised at least $20,000,000 in capital. Cedars shall also have a right to participate in any private offering of Enviro's equity securities and purchase for cash that number of securities issued to maintain Cedars' pro rata ownership in Enviro on a fully diluted basis.

Pursuant a license and supply agreement between Enviro and Tracon Pharmaceuticals, Inc., 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. Until such time as Tracon has received all of the Cash Consideration (as defined in the Enviro-Tracon license agreement), 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 7% on a fully diluted and converted basis of all common and preferred shares of Enviro (or its successor). Cash Consideration under the Enviro-Tracon license agreement consists of an upfront fee of $100,000, an additional $500,000 upon it's 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 it's 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.

If the Company is not able to raise funds sufficient to terminate these anti-dilution rights granted to Cedars and Tracon, then investors in the Company's securities could experience severe dilution in proportion to Cedars and Tracon. The presence of these anti-dilution rights granted to Cedars and Tracon may also discourage third-party investors from investing in the Company's securities.

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 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 prospectus 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

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. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. 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. In addition, it is anticipated that the California Privacy Rights Act of 2020 (CPRA), effective January 1, 2023, would expand the CCPA. The CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. 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

If you purchase common stock in this offering, you will suffer immediate dilution of your investment.

The initial public offering price per share of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share. Therefore, if you purchase common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. Based on an initial public offering price of $4.00 per share, you will experience immediate dilution of $3.63 per share, representing the difference between our pro forma as adjusted net tangible book value per share after this offering and the initial public offering price per share. After this offering, we will also have outstanding options and warrants to purchase shares of our common stock, in some cases with exercise prices lower than the initial public offering price. To the extent these outstanding options or warrants are exercised, there will be further dilution to investors in this offering. For further information regarding the dilution resulting from this offering, see the section titled "Dilution" in this prospectus.

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 following this offering, the market price of our common stock could decline significantly.

Upon the closing of this offering, we will have 12,841,937 outstanding shares of common stock, after giving effect to the conversion of all $0.9 million of our outstanding convertible notes and notes payable – officers, plus accrued and unpaid interest, into 369,248 shares of common stock, assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding stock options. Of these shares, the shares sold in this offering will be freely tradable and the remaining shares of common stock will be available for sale in the public market beginning after the end of the 180th day after the date of this prospectus following the expiration of lock-up agreements between our stockholders and certain of the underwriters for this offering, subject, in the case of our affiliates, to the conditions of Rule 144 under the Securities Act. The representatives, on behalf of the underwriters, may release these stockholders from their lock-up agreements at any time and without notice, which would allow for earlier sales of shares in the public market subject to the conditions of Rule 144 under the Securities Act.

We have reserved 1,650,000 shares of common stock for issuance under our 2023 equity incentive plans (the "2023 Equity Incentive Plan"), of which we will issue a total of $150,000 in options to purchase shares of common stock to our independent directors upon completion of this initial public offering. 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.

In addition, promptly following the closing of this offering, we intend to file a registration statement on Form S-8 registering the shares of common stock subject to options or other equity awards issued or reserved for future issuance under our 2023 Equity Incentive Plan. Shares registered on Form S-8 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, after this offering, the holders of an aggregate of shares of our common stock, or their transferees, will have rights, subject to some 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 these 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 it's the price in this offering or 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 satisfy listing requirements of NYSE American or maintain a listing of our common stock on such exchange.

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 will not be a controlled company following completion of our initial public offering, 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.

Upon completion of this offering, John S. Yu, our Chairman, and CEO, will be able to exercise voting rights with respect to an aggregate of 5,316,572 shares of common stock, which represents approximately 43.7% of the voting power of our outstanding capital stock. As a result, Dr. Yu has the ability to 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 concentrated control 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 concentrated control 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 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.

Upon completion of this offering, our executive officers, directors, and current beneficial owners of 5% or more of our capital stock and their respective affiliates will, in the aggregate, beneficially own 52.0% of our outstanding common stock, based on the number of shares of our capital stock outstanding as of June 30, 2024, assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options. 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 at which shares are being sold in this offering 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 this offering 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 this offering, 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 this offering, in a manner that does not produce value or that loses value. See the section titled "Use of Proceeds" for additional information.

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

An active trading market for our common stock may not develop and you may not be able to resell your shares at or above the initial offering price, if at all.

This offering constitutes the initial public offering of our common stock, and no public market has previously existed for our common stock. Our common stock has been approved for listing on NYSE American. There can be no assurance that an active trading market for shares of our common stock will develop or be sustained after this offering is completed. The initial offering price was determined by negotiations among the lead underwriters and us. Among the factors considered in determining the initial public offering price were our future prospects and the prospects of our industry in general, our financials and certain other financial and operating information in recent periods, and the market prices of securities and certain financial and operating information of companies engaged in activities similar to ours. However, there can be no assurance that, following the completion of this offering, the shares of our common stock will trade at a price equal to or greater than the public offering price.

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 following this offering is likely to 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 in this "Risk Factors" section and elsewhere in this prospectus, 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 the COVID-19 pandemic and the recent outbreak of hostilities 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 after the completion of this offering, 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 will incur significantly increased costs as a result of operating as a company whose common stock is publicly traded in the United States, and our management will be required to devote substantial time to new compliance initiatives.

As a public company in the United States, we will incur significant legal, accounting, and other expenses that we did not incur previously. 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 prospectus. In particular, in this prospectus, 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.

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, 2023, we had federal and state net operating loss, or NOLs, carryforwards of approximately $2.0 million, respectively. 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 this offering and/or 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.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine.

U.S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. In February 2022, Russia launched a full-scale military invasion of Ukraine. Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets. Additionally, Russia's prior annexation of Crimea, recognition of two separatist republics in the Donetsk and Luhansk regions of Ukraine, subsequent military interventions in Ukraine, and attempted annexation of four oblasts in Ukraine have led to sanctions and other penalties being levied by the United States, European Union and other countries against Russia, Belarus, the Crimea Region of Ukraine, the so-called Donetsk People's Republic, and the so-called Luhansk People's Republic, including agreement to remove certain Russian financial institutions from the Society for Worldwide Interbank Financial Telecommunication (SWIFT) payment system. Additional potential sanctions and penalties have also been proposed and/or threatened. Russian military actions and the resulting sanctions could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds. Any of the abovementioned factors could affect our business, prospects, financial condition, and operating results. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this prospectus.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding 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.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue," or the negative of these terms or other similar expressions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- our use of the net proceeds from this offering;
- 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;
- the ability of our planned clinical trials for are target drugs to be sufficient for regulatory approval in the United States;
- our ability to retain the continued service of our key professionals and to identify, hire, and retain additional qualified professionals;
- 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 commercialization of 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.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations, and prospects and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties, and assumptions described in the section titled "Risk Factors" and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events, or otherwise.

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 prospectus, 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.

USE OF PROCEEDS

Assuming we complete an $6.2 million offering, we estimate that we will receive net proceeds from this offering of approximately $5.6 million (or approximately $6.5 million if the underwriters' option to purchase additional shares of our common stock is exercised in full) based on the initial public offering price of $4.0 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering to fund Phase 1 and Phase 2 clinical trials of our product candidate ENV 105 and preclinical candidates including KROS 101, potential acquisition or in-licensing activities, and working capital and general corporate purposes. The funds are expected to be used as follows:

- approximately $1.0 million to fund the clinical trials of our lead product candidate ENV 105;
- approximately $0.7 million to pay outstanding accounts payable; and
- any remaining proceeds for working capital and general corporate purposes.

The use of proceeds could differ from the estimates above if the enrollment in our clinical trials is greater than expected in the first 12 months of the trials. If that happens, we may need to use additional proceeds to fund our clinical trials.

In order to complete the Phase 2 trial for prostate cancer for ENV 105 we anticipate we will need $1.7 million. The ENV 105 Phase 1 trial for non-small cell lung cancer will be completed with no additional funding as it is fully funded by an external source. For preclinical development of KROS 101, KROS 301 and KROS 401, we estimate requiring $3.2 million. Aside from our ongoing trials, we intend to advance one drug at a time, depending on availability of funds. There can be no guarantee that we will be successful in completing the clinical trials or reaching the required milestones.

We believe, based on our current operating plan, that the net proceeds from this offering will be sufficient to fund our operations for at least the next 12 months. As a result, and as we will require approximately $5.5 million in additional funding to support our drug development efforts during months 13-24, we will be seeking to raise additional capital following completion of the IPO.

Our expected use of proceeds from this offering described above represents our current intentions based on our present plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the closing of this offering or the actual amounts that we will spend on the uses set forth above. In the case that the net proceeds from this offering not be sufficient for us to fund any/all of our current in-development products through regulatory approval, we may need to raise additional capital to commercialize our current in-development products and to develop any future product candidates.

The amounts and timing of our actual expenditures will depend on numerous factors, including the time and cost necessary to conduct our planned clinical trials, the results of our planned clinical trials and other factors described in the section titled "Risk Factors" in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes. We will have broad discretion over how to use the net proceeds to us from this offering.

DIVIDEND POLICY

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.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and investments and capitalization as of June 30, 2024:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the automatic conversion of all of our outstanding convertible notes, notes payable – officers and the related accrued interest into 369,248 shares of our common stock in connection with the closing of this offering, (ii) the conversion of certain accounts payable into 312,500 shares of our common stock upon effectiveness of our registration statement; and (iii) the conversion of amounts due to related parties into 1,664 shares of our common stock upon effectiveness of our registration statement; and (iv) the conversion of amounts due to an officer into 45,885 shares of our common stock upon effectiveness of our registration statement; and
- on a pro forma, as adjusted basis, giving effect to (i) the pro forma adjustments set forth above and (ii) our receipt of net proceeds from the sale of 1,550,000 shares of common stock in this offering at the initial public offering price of $4.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with the sections titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Description of Capital Stock," and our financial statements and the related notes included elsewhere in this prospectus.

	As of June 30, 2024		
	Actual (Unaudited)	Pro Forma (Unaudited)	Pro Forma As Adjusted (Unaudited)
	(In thousands, except share amounts)		
Cash	$ 21	$ 21	$ 5,621
Notes payable - officers	102	-	-
Convertible notes payable, net of debt discount of $66	677	-	-
Shareholders' Equity (Deficit)			
Common stock, par value $0.001, 100,000,000 shares authorized; 10,562,640 shares issued and outstanding; 11,291,937 shares issued and outstanding pro forma; 12,841,937 shares issued and outstanding pro forma as adjusted	11	11	13
Additional paid-in capital	4,123	5,958	11,556
Accumulated deficit	(6,788)	(6,854)	(6,854)
Total shareholder's equity (deficit)	$ (2,654)	$ (885)	$ 4,715
Total Capitalization	$ (1,875)	$ (885)	$ 4,715

The number of shares of our common stock to be issued and outstanding after this offering pro forma and pro forma as adjusted in the table above is based on 10,562,640 shares of common stock outstanding as of June 30, 2024, after giving effect to the automatic conversion of all of our outstanding convertible notes, notes payable – officers and the related accrued interest, along with certain accounts payable into a total of 729,297 shares of common stock upon effectiveness of our registration statement, and excludes:

- 150,000 shares of our common stock issuable upon the exercise of outstanding warrants as of June 30, 2024, with a weighted-average exercise price of $4.17 per share; and
- 1,650,000 shares of our common stock are reserved for future issuance under our 2023 Equity Incentive Plan, which became effective upon effectiveness of this registration statement of which this prospectus forms a part, as well as any future increases in the number of shares of common stock reserved for issuance under our 2023 Equity Incentive Plan. See the section entitled "Equity Incentive Plans" below.

DILUTION

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the initial public offering price per share of common stock and the pro forma as adjusted net tangible book value per share immediately after this offering.

As of June 30, 2024, we had a historical net tangible book value (deficit) of $(2.7) million, or $(0.25) per share of common stock based on the 10,562,640 shares of common stock outstanding as of such date. Our historical net tangible book value (deficit) per share represents total tangible assets less total liabilities, which is not included within permanent equity, divided by the number of shares of common stock outstanding as of June 30, 2024.

Our pro forma net tangible book value as of June 30, 2024, was $(0.9) million, or $(0.08) per share. Pro forma net tangible book value per share represents the amount of our total tangible assets less our total liabilities, divided by 11,291,937 shares of common stock outstanding as of such date, after giving effect to the automatic conversion of all of our convertible notes payable, amounts due to related parties and certain accounts payable as of June 30, 2024 into 729,297 shares of our common stock upon the closing of this offering.

After giving effect to the sale by us of shares of common stock in this offering at the initial public offering price of $4.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of June 30, 2024 would have been $4.7 million, or $0.37 per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of $0.45 per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of $3.63 per share to investors purchasing common stock in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash paid by an investor for a share of common stock in this offering. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		$ 4.00
Historical net tangible book value (deficit) per share as of June 30, 2024	(0.25)	
Pro forma increase in historical net tangible book value per share attributable to the pro forma transactions described in the preceding paragraphs	0.17	
Pro forma net tangible book value per share as of June 30, 2024	(0.08)	
Increase in pro forma as adjusted net tangible book value per share attributable to investors purchasing shares in this offering	0.45	
Pro forma as adjusted net tangible book value per share after this offering		0.37
Dilution in pro forma as adjusted net tangible book value per share to investors purchasing shares in this offering		$ 3.63

If the underwriters exercise their option to purchase additional shares of common stock in full, the pro forma net tangible book value per share, as adjusted to give effect to this offering, would be $0.45 per share, and the dilution in pro forma net tangible book value per share to investors in this offering would be $3.55 per share.

The following table summarizes, as of June 30, 2024 (amounts in thousands, except share and price per share amounts):

- the total number of shares of common stock purchased from us by our existing stockholders (including convertible noteholders whose notes automatically convert following completion of this offering) and by investors purchasing shares in this offering;
- the total consideration paid to us by our existing stockholders and by investors purchasing shares in this offering, before deducting underwriting discounts and commissions and estimated offering expenses payable by us in connection with this offering; and
- the average price per share paid by existing stockholders for shares issued prior to this offering and by investors purchasing shares in this offering.

	Shares Purchased		Total Consideration		Average Price Per
	Number	Percent	Amount	Percent	Share
Existing stockholders	11,291,937	87.9%	$ 4,399	41.5%	$ 0.39
New investors	1,550,000	12.1%	6,200	58.5%	4.00
Total	12,841,937	100.0%	$ 10,599	100.0%	

The foregoing discussion and table above (other than the historical net tangible book value calculation) are based on 11,291,937 shares of common stock outstanding as of June 30, 2024, after giving effect to the automatic conversion of all of our outstanding convertible notes, notes payable – officers and the related accrued interest, amounts due to related parties and an officer, and certain accounts payable, as of June 30, 2024, into 729,297 shares of our common stock upon the closing of this offering, and excludes:

- 150,000 shares of our common stock issuable upon the exercise of outstanding warrants as of December 31, 2023, with a weighted-average exercise price of $4.17 per share;
- 1,650,000 shares of our common stock reserved for future issuance under our 2023 Equity Incentive Plan, which became effective once the registration statement of which this prospectus forms a part was declared effective, as well as any future increases in the number of shares of common stock reserved for issuance under our 2023 Equity Incentive Plan.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with "Selected Financial Data" and our financial statements and related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus 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 "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note 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 we expect will target drug resistance and checkpoints of immune suppression. As of the date of this prospectus, 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 $0.6 million and $1.8 million for the six months ended June 30, 2024 and for the year ended December 31, 2023, respectively. As of June 30, 2024, we had an accumulated deficit of $6.8 million. 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.

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, a number of governmental orders and other public health guidance measures have been implemented across much of the United States, including in the locations of our office, clinical trial sites and third parties on whom we rely. As the COVID-19 pandemic started to spread in the first half of 2020, our clinical trial sites reported it had the most impact on patient care as facilities were generally ill prepared to conduct business as usual; adequate clinical evaluations, physical exams and tests were either absent or drastically reduced. Our clinical trial sites further reported that their institutions better adjusted to pandemic conditions beginning in the second half of 2020. As our corporate operations presently take place entirely virtually, COVID-19 has had no material impact on our operations to date. As we begin our clinical trials, we will continue to monitor the impact COVID-19 may have on the operations of our trials. We have taken measures to secure our research and development project activities, and work in laboratories has been organized to reduce the risk of COVID-19 transmission.

We will not generate revenue from product sales unless and until we successfully complete clinical development 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 or 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.

The report of our independent registered public accounting firm on our financial statements for the years ended December 31, 2022 and 2023 included an explanatory paragraph indicating that there was substantial doubt about our ability to continue as a going concern. See Note 1 to our annual financial statements appearing at the end of this prospectus for additional information on our assessment.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, contemplating 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 incurred a net loss of $0.6 million during the six months ended June 30, 2024, and $1.8 million during the year ended December 31, 2023, and had a shareholders' deficit of $2.7 million as of June 30, 2024. These factors raise substantial doubt, as defined under GAAP, about the Company's ability to continue as a going concern for the next 12 months. Management's plan 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 related to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

At June 30, 2024, the Company had cash on hand in the amount of $0.02 million. The ability to continue as a going concern is dependent on the Company attaining and maintaining profitable operations in the future and raising additional capital to meet its obligations and repay its liabilities arising from normal business operations when they come due. Since inception, the Company has funded its operations primarily through equity and debt financings and it expects to continue to rely on these sources of capital in the future.

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.

Share Exchange between Kairos and Enviro

In June 2021, Enviro and Kairos completed the Enviro-Kairos share exchange, whereby 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. After the closing, Enviro became a wholly owned subsidiary of Kairos.

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 audited financial statements appearing elsewhere in this prospectus, we believe the following are the critical accounting policies used in the preparation of our financial statements that require significant estimates and judgments.

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, 2022 and 2023, and June 30, 2024, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Off-Balance Sheet Arrangements

During the years ended December 31, 2022 and 2023, and the six months ended June 30, 2024, we did not have, and we do not currently have, any off-balance sheet arrangements (as defined under SEC rules).

Quantitative and Qualitative Disclosures about Market Risk

Our cash is held on deposit in demand accounts at a large financial institution in amounts, at times, in excess of the Federal Deposit Insurance Corporation, or FDIC, insurance coverage limit of $250,000 per depositor, per FDIC-insured bank, per ownership category. We have reviewed the consolidated financial statements of this institution and believe it has sufficient assets and liquidity to conduct its operations in the ordinary course of business with little or no credit risk to us. Financial instruments that potentially subject us to concentrations of credit risk principally consist of cash equivalents. We limit our credit risk associated with cash equivalents by placing investments in highly rated money market funds.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2022 or 2023, or the six months ended June 30, 2024.

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 prospectus.

Components of Results of Operations

Net Sales

We have not generated any sales to date. There was no revenue recorded from any sources during the years ended December 31, 2022 and 2023, and the six months ended June 30, 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 patent technologies that are subject to the Kairos-Cedars license agreements, described above.

We are engaged in rolling out 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 the COVID-19 pandemic or similar 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 and IPO-related 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 Three Months Ended June 30, 2023 and 2024

The following table summarizes our results of operations for the three months ended June 30, 2023 and 2024 (in thousands):

Operating Expenses:	June 30, 2023	June 30, 2024
Research and development	$ 36	$ 63
General and administrative	176	159
Total operating expenses	212	222
Loss from operations	(212)	(222)
Other expenses:		
Interest expense	(14)	(12)
Debt discount amortization	(10)	(19)
Total other expenses	(24)	(31)
Net loss	$ (236)	$ (253)

Research and Development Expenses

The table below summarizes our research and development expenses for the three months ended June 30, 2023 and 2024 (in thousands):

Research and Development Expenses:	June 30, 2023	June 30, 2024
Clinical and related expenses	$ 36	$ 63
Total research and development expenses	$ 36	$ 63

Research and development expenses were $0.04 million and $0.06 million for the three months ended June 30, 2023 and 2024, respectively. The increase in 2024 primarily resulted from expenses relating to the beginning of our Phase 2 clinical trial for our lead product candidate ENV 105.

General and Administrative Expenses

The table below summarizes our general and administrative expenses for the three months ended June 30, 2023 and 2024 (in thousands):

General and Administrative Expenses:	June 30, 2023	June 30, 2024
Patent related expenses	$ -	$ 1
Legal fees	-	1
Accounting fees	79	50
Other professional fees	17	26
Fees relating to license agreements	33	32
Insurance expense	5	9
Amortization expense	40	40
Other expenses	2	-
Total general and administrative expenses	$ 176	$ 159

General and administrative expenses were $0.2 million and $0.2 million for the three months ended June 30, 2023 and 2024, respectively. There were no significant changes between periods.

Other Expenses

Other expenses were $0.02 million and $0.03 million for the three months ended June 30, 2023 and 2024, respectively. The increase of $0.01 million in 2024 was due to the increase in debt discount amortization in 2024.

Results of Operations

Comparison of the Six months Ended June 30, 2023 and 2024

The following table summarizes our results of operations for the six months ended June 30, 2023 and 2024 (in thousands):

Operating Expenses:	June 30, 2023	June 30, 2024
Research and development	$ 42	$ 228
General and administrative	296	286
Total operating expenses	338	514
Loss from operations	(338)	(514)
Other expenses:		
Interest expense	(24)	(23)
Debt discount amortization	(20)	(39)
Total other expenses	(44)	(62)
Net loss	$ (382)	$ (576)

Research and Development Expenses

The table below summarizes our research and development expenses for the six months ended June 30, 2023 and 2024 (in thousands):

Research and Development Expenses:	June 30, 2023	June 30, 2024
Clinical and related expenses	$ 42	$ 228
Total research and development expenses	$ 42	$ 228

Research and development expenses were $0.04 million and $0.2 million for the six months ended June 30, 2023 and 2024, respectively. The increase in 2024 primarily resulted from expenses relating to the beginning of our Phase 2 clinical trial for our lead product candidate ENV 105.

General and Administrative Expenses

The table below summarizes our general and administrative expenses for the six months ended June 30, 2023 and 2024 (in thousands):

General and Administrative Expenses:	June 30, 2023	June 30, 2024
Patent related expenses	$ 21	$ 9
Legal fees	-	2
Accounting fees	98	72
Other professional fees	28	32
Fees relating to license agreements	58	64
Insurance expense	6	21
Amortization expense	80	80
Other expenses	5	6
Total general and administrative expenses	$ 296	$ 286

General and administrative expenses were $0.3 million and $0.3 million for the six months ended June 30, 2023 and 2024, respectively. There were no significant changes between periods.

Other Expenses

Other expenses were $0.04 million and $0.06 million for the six months ended June 30, 2023 and 2024, respectively. The increase of $0.02 million in 2024 was due to the increase in debt discount amortization in 2024.

For the Years Ended December 31, 2022 and 2023

The following table summarizes our results of operations for the years ended December 31, 2022 and 2023 (in thousands):

Operating Expenses:	December 31, 2022	December 31, 2023
Research and development	$ 87	$ 82
General and administrative	484	1,632
Total operating expenses	571	1,714
Loss from operations	(571)	(1,714)
Other expenses:		
Interest expense	(51)	(42)
Debt discount amortization	(408)	(56)
Financing costs	(20)	-
Total other expenses	(479)	(98)
Net loss	$ (1,050)	$ (1,812)

Research and Development Expenses

The table below summarizes our research and development expenses for the years ended December 31, 2022 and 2023 (in thousands):

Research and Development Expenses:	December 31, 2022	December 31, 2023
Clinical and related expenses	$ 87	$ 82
Total research and development expenses	$ 87	$ 82

Research and development expenses were $0.1 million and $0.1 million for the years ended December 31, 2022 and 2023, respectively. There were no significant changes between periods.

General and Administrative Expenses

The table below summarizes our general and administrative expenses for the years ended December 31, 2022 and 2023 (in thousands):

General and Administrative Expenses:	December 31, 2022	December 31, 2023
Patent related expenses	$ 110	$ 45
Fair value of common stock issued to shareholders	-	913
Legal fees	2	89
Accounting fees	28	154
Other professional fees	45	42
Fees relating to license agreements	112	176
Insurance expenses	20	29
Amortization expense	160	160
Other expenses	7	24
Total general and administrative expenses	$ 484	$ 1,632

General and administrative expenses were $0.5 million and $1.6 million for the years ended December 31, 2022 and 2023, respectively, representing an increase of $1.1 million. Significant changes between periods consisted of a $0.9 million increase in the fair value of common shares issued in 2023 to shareholders, as no common shares were issued in 2022.

Other Expenses

Other expenses were $0.5 million and $0.1 million for the years ended December 31, 2022 and 2023, respectively. The decrease of $0.4 million in 2023 was primarily due to decreased debt discount amortization in 2023.

Liquidity and Capital Resources

Going Concern

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, we have not yet generated revenues and have incurred recurring net losses since inception. During the six months ended June 30, 2024, we incurred a net loss of $0.6 million and had a shareholders' deficit of $2.7 million as of June 30, 2024. These factors raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to raise additional funds and implement our strategies. The financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

As of June 30, 2024, we had cash on hand in the amount of $0.02 million. The ability to continue as a going concern is dependent on us raising additional capital and attaining and maintaining profitable operations in the future to meet our obligations and repay our liabilities arising from normal business operations when they come due. Since inception, we have funded our operations primarily through equity and debt financings and we expect to continue to rely on these sources of capital in the future.

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 us. Even if we are 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 the case of equity financing.

Cash Flows for the Six months Ended June 30, 2023 and 2024

The table below summarizes our cash flow activities for the six months ended June 30, 2023 and 2024 (in thousands):

	Six months Ended June 30,	
Net cash provided by (used in):	**2023**	**2024**
Operating activities	$ (76)	$ (132)
Investing activities	-	-
Financing activities	(129)	60
Net increase (decrease) in cash	$ (205)	$ (72)

Operating Activities

During the six months ended June 30, 2023, we used cash from operating activities of $0.08 million, compared to $0.1 million used during the six months ended June 30, 2024. During the six months ended June 30, 2024, we incurred a net loss of $0.6 million and had non-cash expenses of $0.1 million, compared to a net loss of $0.4 million and non-cash expenses of $0.1 million during the six months ended June 30, 2023. The primary non-cash expense incurred during both periods was amortization expense, totalling $0.08 million during the six months ended June 30, 2023 and 2024, respectively. The net change in assets and liabilities during the six months ended June 30, 2023 provided cash of $0.2 million, compared to $0.3

million provided during the six months ended June 30, 2024. The source of cash for the six months ended June 30, 2023 and 2024 was the increase in accounts payable and accrued expenses.

Investing Activities

There was no cash used in investing activities for the six months ended June 30, 2023 and 2024.

Financing Activities

Net cash (used in) provided by financing activities for the six months ended June 30, 2023 and 2024 was $(0.1) million and $0.1 million, respectively. For the six months ended June 30, 2023 and 2024, cash used in financing activities consisted of payments of deferred offering costs of $0.1 and $0.04 million, respectively. For the six months ended June 30, 2024, cash provided by financing activities consisted of $0.1 million from notes payable – officers.

Cash Flows for the Years Ended December 31, 2022 and 2023

The table below summarizes our cash flow activities for the years ended December 31, 2022 and 2023 (in thousands):

	Years Ended December 31,	
Net cash provided by (used in):	2022	2023
Operating activities	$ (353)	$ 81
Investing activities	-	-
Financing activities	717	(425)
Net increase (decrease) in cash	$ 364	$ (344)

Operating Activities

During the year ended December 31, 2022, we used cash from operating activities of $0.4 million, compared to $0.08 million provided during the year ended December 31, 2023. During the year ended December 31, 2022, we incurred a net loss of $1.1 million and had non-cash expenses of $0.6 million, compared to a net loss of $1.8 million and non-cash expenses of $1.1 million during the year ended December 31, 2023. Non-cash expenses during 2022 included amortization expense of $0.2 million and amortization of debt discount of $0.4 million. Non-cash expenses during 2023 included amortization expense of $0.2 million, amortization of debt discount of $0.06 million and the fair value of common stock issued to shareholders of $0.9 million. The net change in assets and liabilities during the year ended December 31, 2022 provided cash of $0.1 million, compared to $0.8 million provided during the year ended December 31, 2023. The primary source of cash for both years resulted from the increase in accounts payable and accrued expenses.

Investing Activities

There was no cash used in investing activities for the years ended December 31, 2022 and 2023.

Financing Activities

Net cash provided by (used in) financing activities for the years ended December 31, 2022 and 2023 was $0.7 million and $(0.4) million, respectively. For the year ended December 31, 2022, cash provided by financing activities consisted of proceeds from the issuance of convertible notes payable of $0.9 million. Cash used in financing activities during the year ended December 31, 2022 related to the repayment of a note payable of $0.03 million, the repayment of an advance from a related party of $0.01 million and the payments of deferred offering costs of $0.06 million and debt issuance costs of $0.1 million. For the year ended December 31, 2023, there was no cash provided by financing activities. Cash used in financing activities in 2023 consisted of the payment of deferred offering costs of $0.4 million.

Debt Agreements

Advances from 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 $0.01 million, all of which was 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 million remained outstanding.

Convertible Notes Payable

During the year ended December 31, 2022, the Company entered into several convertible note payable agreements with certain investors in the aggregate total of $0.7 million. The convertible 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 following the date of issuance of the notes, the Company will have the choice of paying off the principal plus all accrued and unpaid interest, or the note's principal balance will 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 relating to the agreements, net of expenses, were $0.6 million. The convertible note offerings were completed pursuant to an exemption from registration under Rule 506(b) of the Securities Act of 1933, as amended (the "Securities Act"). Boustead Securities, LLC acted as placement agent in each of the June and September 2022 private placements and received $0.09 million and $0.02 million cash compensation, respectively, and five-year warrants to purchase shares of common stock equal to 7.0% of the number of the Conversion Shares at an exercise price equal to the conversion price.

During the year ended December 31, 2023, as we did not close our 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 $0.07 million. As of December 31, 2023, $0.7 million of principal was outstanding on the notes and $0.06 million of accrued and unpaid interest. As of June 30, 2024, $0.7 million of principal was outstanding on the notes and $0.08 million of accrued and unpaid interest.

Notes Payable - Officers

During the six months ended June 30, 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 one year from the issuance date, with the due dates ranging from April 2025 to August 2025.

The officers have agreed to convert the amounts due under the notes into approximately 25,792 shares of the Company's common stock, effective upon the closing of the Company's IPO and based on the amount owed at June 30, 2024, assuming a $4.00 per share conversion price. The conversion price of the shares will be equal to the per share IPO price.

Conversion of Accounts Payable

Subsequent to December 31, 2023, we entered into agreements with Cedars-Sinai Medical Center ("Cedars") under which Cedars agreed to convert $0.8 million of the $1.0 total accounts payable due to them into 312,500 shares of our common stock, with such conversion to occur upon the closing of the Company's IPO. The conversion price of the shares will be equal to 60% of the per share IPO price.

Conversion of Amounts Due to Related Parties

Subsequent to December 31, 2023, two officers and shareholders agreed to convert the $0.004 million due to them into 1,664 shares of the Company's common stock, effective upon the closing of the Company's IPO. The conversion price of the shares will be equal to the per share IPO purchase price.

As of June 30, 2024, an officer has agreed to convert $0.2 million of accounts payable owed primarily for past services into 45,885 shares of the Company's common stock, effective upon the closing of the Company's IPO. The conversion price of the shares will be equal to the IPO per share purchase price times a multiple of 1.2, as per the officer's employment agreement.

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 believe that our existing cash, plus the net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. 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. We expect that we will require additional funding to complete the clinical development and commercialize 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 your rights as a 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.

Contractual Obligations and Commitments

Exclusive License Agreements with Cedars-Sinai Medical Center ("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 Therapeutics, Inc. ("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.

License Agreement with Tracon Pharmaceutical, Inc.

On May 21, 2021, Enviro entered into a License Agreement with Tracon Pharmaceutical, Inc. ("Tracon"). Pursuant to the Tracon License Agreement, Tracon granted 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" (all as defined or described in the Tracon License Agreement).

Agreement with former Chief Financial Officer

We have an agreement with our former Chief Financial Officer that requires us to pay $0.05 million upon the completion of raising more than $0.9 million in a debt or an equity financing. No amount was owed at December 31, 2022 or 2023. In addition, on September 27, 2023, we have entered into an employment agreement with our Chief Financial Officer, which will become effective upon completion of this initial public offering.

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 prospectus, 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 prospectus, 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, we learned that the National Cancer Institute / National Institutes of Health ("NIH") 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.

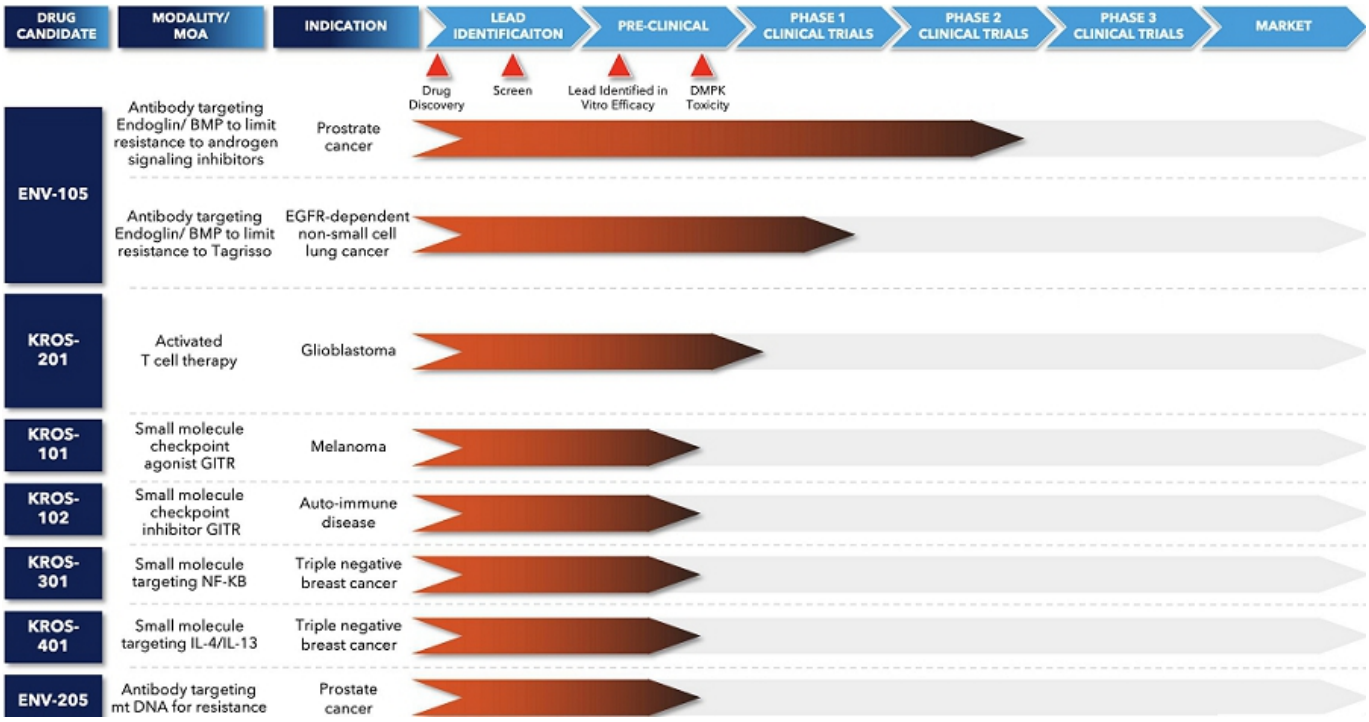
We are also developing **KROS 102**, **KROS 301**, and **KROS 401**. **KROS 102** is a GITR ligand antagonist designed to increase inhibitory Treg functions while hampering T effector cell numbers and function. **KROS 301** is a tumor targeting small molecule and checkpoint inhibitor with two distinct 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 prospectus, **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 prospectus, 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. The projected market share of $74.3 billion by 2027 for chemotherapy alone, support an effectively large market share for ENV205, as the only biologic reported to restore chemotherapy sensitivity in preclinical studies.

Our Market Opportunity

Global cancer drug spending is expected to reach $311.2 billion by 2026 driven largely by the growth of immuno-oncology (EvaluatePharma World Preview 2020). Global immunotherapy market estimates show significant compound growth with sales expectations ranging from $94.7-$126.9 billion by 2026, exhibiting a CAGR of up to 20.2% from 2020 (Grand View Res.). 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 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 over 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 at $1.51 billion in 2021. 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 $31.4 billion in 2021 and anticipated to be $148 billion in 2020 with a CAGR of 18.81% from 2022 to 2030 (Precedence Research).

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 (Grandview 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 estimated at $39.3 billion in 2021 and is expected to reach $42.1 billion in 2022 (Grandview 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 30% of all cancer, 20% of AIDS, and 30% of COPD patients. Cachexia is an unfortunate 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 cancer cachexia therapeutics market is estimated to reach above $1 billion in the U.S. alone. The application of ENV 105 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.

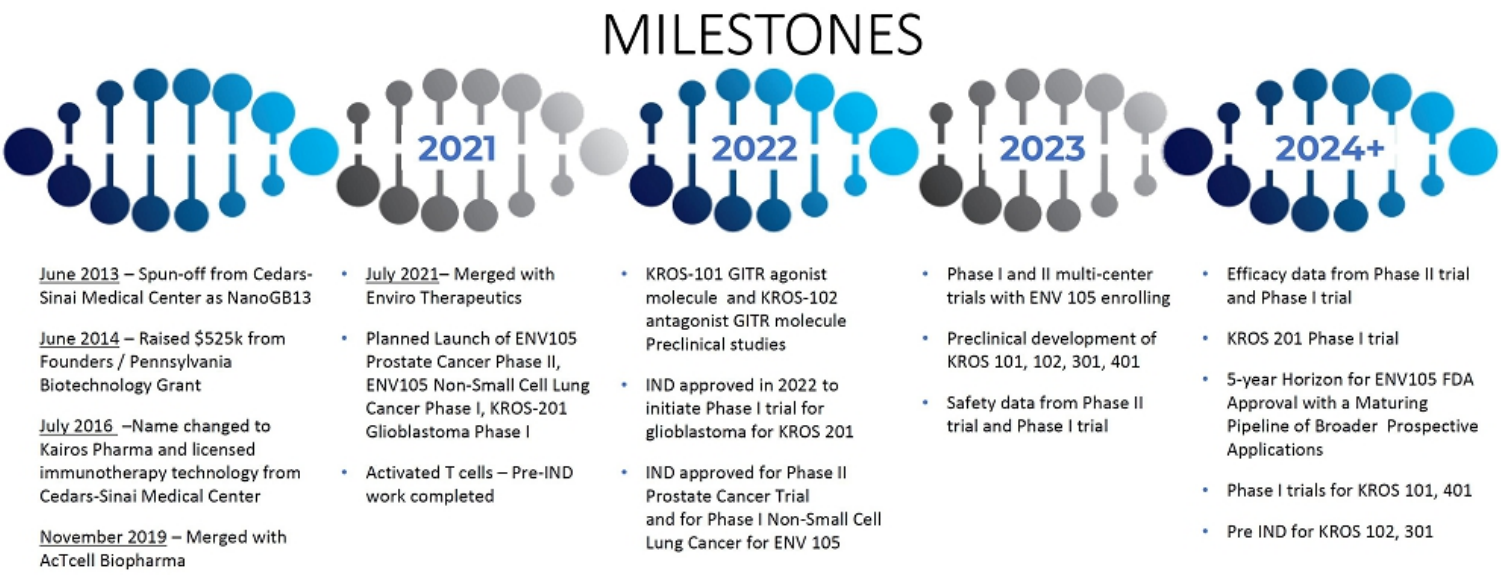
Our Strategy

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, and 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 patent 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 (which include 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 the Cedars based on the following milestones: (i) successful completing of Phase 1 clinical trial; (ii) the successful completing 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, Kairos is required to (i) pay an initial license fee of $15,000 in total, (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 shall 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 90 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 give Enviro options to enter into an Exclusive Agreement with Cedars which would grant Enviro exclusive licensing rights (which include 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 Phase 1 trial within four years of the Effective Date.

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

The Exclusive License Agreement between Enviro and Cedars was made effective on June 2, 2021. 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 shall pay an upfront license fee, plus an additional fee when Enviro has raised at least $250,00,00 in capital company-wide for any program or purpose; provided, however, will only have to pay such fee once between both Enviro-Cedars license agreements. Enviro shall also reimburse Cedars for the costs incurred in 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 September 16, 2024. Together, Kairos and Enviro owe a total of approximately $950,000 to Cedars, of which $750,000 will be converted into 312,500 shares of common stock, or 60% of the IPO price, upon closing of the IPO. Cedars shall also 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.

Enviro License and Supply Agreement with Tracon Pharmaceuticals, Inc.

On May 21, 2021, Enviro 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." Dr. Bhowmick, our Chief Scientific and Enviro's CEO, is a consultant at Tracon Pharmaceuticals, Inc.

Pursuant to the Enviro-Tracon license agreement, Enviro paid Tracon an upfront fee of $100,000, and is 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 is 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.

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. 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 is equal to 1.41229% of the issued and outstanding shares of Kairos on a fully diluted and converted basis). 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). Notwithstanding the foregoing, if Tracon receives the full cash consideration within six months of the effective date of the Enviro-Tracon license agreement, then Tracon shall automatically return to Enviro (or any successor entity, if applicable) a number of shares of the restricted common stock of Enviro (or its successor) such that upon such return of shares Tracon shall possess an amount of shares in Enviro (or its successor) equal to 2% on a fully-diluted and converted basis relative to the other Enviro shareholders who exchanged their shares in the Enviro-Kairos share exchange. The returned portion of the Tracon-Enviro equity shall automatically be terminated, cancelled and of no further force and effect.

Pursuant to the Enviro-Tracon license 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

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
ENDOGLIN ANTIBODIES	8,221,753	GRANTED	ENV 105	Product	2030-03-31	United States of America
ENDOGLIN ANTIBODIES	9,150,652	APPLICATION	ENV 105	Method of treatment	2029-09-30	United States of America
ENDOGLIN ANTIBODIES	9,944,714	GRANTED	ENV 105	Composition of matter	2030-03-31	United States of America
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)
ANTIBODY FORMULATIONS AND USES THEREOF	1538/DELNP/2015	APPLICATION	ENV 105	Both a Product and a Method of Treatment Patent	2033-09-05	India
ANTIBODY FORMULATIONS AND USES THEREOF	6445671	GRANTED	ENV 105	Both a Product and a Method of Treatment Patent	2033-09-05	Japan
ANTIBODY FORMULATIONS AND USES THEREOF	6602446	GRANTED	ENV 105	Both a Product and a Method of Treatment Patent	2033-09-05	Japan
ANTIBODY FORMULATIONS AND USES THEREOF	368996	GRANTED	ENV 105	Both a Product and a Method of Treatment Patent	2033-09-05	Mexico
ANTIBODY FORMULATIONS AND USES THEREOF	10,195,281	GRANTED	ENV 105	Product and Formulation	2034-12-25	United States of America
ANTIBODY FORMULATIONS AND USES THEREOF	1501001224	APPLICATION	ENV 105	Both a Product and a Method of Treatment Patent	2033-09-05	Thailand
ANTIBODY FORMULATIONS AND USES THEREOF	MY-180157-A	GRANTED	ENV 105	Both a Product and a Method of Treatment Patent	2033-09-05	Malaysia
METHODS AND USE OF COMPOUNDS THAT BIND TO RELA OF NF-KB	16804352.9	APPLICATION	KROS 301	Both a Product and a Method of Treatment Patent	2036-06-01	European Patent
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
COMPOSITIONS AND METHODS FOR TREATING FIBROSIS	3194446	GRANTED	KROS 401	Both a Product and a Method of Treatment Patent	2035-09-18	European Patent
COMPOSITIONS AND METHODS FOR TREATING FIBROSIS	7095990	GRANTED	KROS 401	Both a Product and a Method of Treatment Patent	2035-09-18	Japan
COMPOSITIONS AND METHODS FOR TREATING FIBROSIS	10,245,298	GRANTED	KROS 401	Pharmaceutical composition	2035-09-18	United States of America
COMPOSITIONS AND METHODS FOR TREATING FIBROSIS	11,547,738	GRANTED	KROS 401	Method of treatment	2035-09-18	United States of America
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
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

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
COMPOSITIONS AND METHODS FOR TREATING CANCER AND AUTOIMMUNE DISEASES	201980062092.7	APPLICATION	KROS 101 and KROS 102	Both a Product and a Method of Treatment Patent	2039-08-08	China
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
COMPOSITIONS AND METHODS FOR TREATING CANCER AND AUTOIMMUNE	2021-506687	APPLICATION	KROS 101 and KROS 102	Both a Product and a Method of Treatment Patent	2039-08-08	Japan
COMPOSITIONS AND METHODS FOR TREATING CANCER AND AUTOIMMUNE DISEASES	10-2021-7006602	APPLICATION	KROS 101 and KROS 102	Both a Product and a Method of Treatment Patent	2039-08-08	Korea, Republic of (KR)
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
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
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
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
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
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
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
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

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
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
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
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
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
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
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

Pursuant to the Kairos-Cedars license agreements, we have exclusive licensing rights (which include the right to sublicense) to four issued U.S. patents and three patent applications in foreign jurisdictions. Maximum aggregate milestone payment is $2,150,000 when each product exceeds $5,000,000 in cumulative net sales.

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
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
COMPOSITIONS AND METHODS FOR TREATING CANCER AND AUTOIMMUNE	2021-506687	APPLICATION	KROS 101 and KROS 102	Both a Product and a Method of Treatment Patent	2039-08-08	Japan
COMPOSITIONS AND METHODS FOR TREATING CANCER AND AUTOIMMUNE DISEASES	10-2021-7006602	APPLICATION	KROS 101 and KROS 102	Both a Product and a Method of Treatment Patent	2039-08-08	Korea, Republic of (KR)
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
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
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
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
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
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
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
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
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
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

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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
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
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
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

Protecting Our Intellectual Property Rights

We strive to protect our proprietary technology, inventions, and know-how to enhance improvements that are commercially important to the development of our business, including seeking, maintaining, and defending patent rights. We also rely on trade secrets and know-how relating to our proprietary technology platform, on continuing technological innovation and on in-licensing opportunities to develop, strengthen and maintain the strength of our position in the field of immune therapeutics and cell therapy that may be important for the development of our business. We additionally may rely on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available.

Our commercial success depends in part on our ability to: obtain and maintain patent and other protections for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing the valid enforceable patents and intellectual property rights of third parties.

Our ability to stop third parties from making, using, selling, offering to sell, or importing our products depends in large part on the extent to which we have rights under valid and enforceable licenses, patents, or trade secrets that cover these activities. In some cases, these rights may need to be enforced by third party licensors. With respect to Company-licensed intellectual property, we cannot be sure that patents will be granted with respect to any of the pending patent applications or with respect to any patent applications filed in the future, nor can we be sure that any of the existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same. For more information, please see “Risk Factors—Risks Related to Our Intellectual Property.”

In connection with our licensing partners, we seek to protect our proprietary position by, among other things, filing patent applications in the United States and internationally in certain jurisdictions where it is available. For example, in coordination with our licensing partners, we file U.S. and selected foreign patent applications related to proprietary technology, inventions, and improvements that are important to the development of our business. We also intend to seek patent protection, or rely upon trade secret rights, to protect other technologies that may be used to discover and validate targets and that may be used to identify and develop novel products or improvements thereof. We seek protection, in part, through confidentiality and proprietary information agreements.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional application which matures into a granted patent. A U.S. patent also may be accorded a patent term adjustment, or PTA, under certain circumstances to compensate for delays in obtaining the patent caused by the U.S. Patent and Trademark Office. In some instances, such a PTA may result in a U.S. patent term extending beyond 20 years from the earliest date of filing a non-provisional patent application. In addition, in the U.S., the term of a U.S. patent that covers an FDA approved drug may also be eligible for patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Hatch Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any of our issued patents in any jurisdiction where these are available; however, there is no guarantee that the applicable authorities, including the FDA in the U.S., will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

Trademark Protection

We have not yet filed any trademark applications for its wordmarks; however, we intend to file applications for trademark protection in the United States for goods and services, and potentially other relevant jurisdictions, but no assurance can be given as to whether such applications will be granted.

Corporate Reorganizations

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 an Exclusive License Agreement dated August 30, 2019 between AcTcell and Cedars-Sinai Medical Center. AcTcell had no liabilities at the merger date.

John Yu, the Company’s Chairman, Chief Executive Officer and majority 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.

The Company's Enviro Therapeutics, Inc. subsidiary, or Enviro, was incorporated on November 15, 2019 under the law of the state of California and is 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 majority shareholder, Dr. Yu, was also a founder and shareholder of Enviro.

On June 3, 2021, Kairos and Enviro entered into a share exchange 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, described further below under "Business–Intellectual Property."

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).

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 "Good Manufacturing Practices" or 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.

Competition

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical companies and generic drug companies. Many of our potential competitors have greater financial and technical human resources than we do, as well as greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Accordingly, our potential competitors may be more successful than us in obtaining FDA-approved drugs and achieving widespread market acceptance. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases we are targeting could render our product candidates non-competitive or obsolete.

The immunotherapy field is characterized by the rapid evolution of technologies and products and by fierce competition based on the development of compounds, often with similar mechanisms of action. Clinical development plans are further compounded by the possibility of overlapping intellectual property. A wide variety of commercial players, large pharmaceutical companies, established and emerging biotechnology companies, and several not-for-profit entities are actively developing potentially competitive products in immunotherapy and in our lead indications.

With respect to KROS-101, it faces potential competition from several GITR focused monoclonal antibody products that are currently under development, including multiple candidates from large pharmaceutical companies, all of which are either Phase 1 or Phase 2 clinical trial. Another product candidate was discontinued after a completed Phase 1 in 2018.

In the area of targeted immunotherapy, Kairos' KROS-102 candidate will, if successful compete, with several monoclonal antibody-based products that target PD-1 or PD-L1 proteins. Such PD-1 or PD-L1 inhibitors activate the immune system to attack tumors and are used to treat certain types of cancer. Currently, there are multiple marketed drugs targeting these same proteins produced by large pharmaceutical companies. In contrast to currently marketed drugs from these large pharmaceutical companies, KROS-101 is a small molecule which is expected to be significantly less expensive to manufacture than a monoclonal antibody-based product.

In the area of cell therapy only two products produced by large pharmaceutical companies have been approved for marketing in the United States, but we estimate that more than 150 clinical trials are currently in progress. One such product is a treatment for B-cell lymphoma, and another is a treatment for large B-cell lymphoma. Both of these therapies are based on CAR T technology where specially altered T cells are used to fight cancer. A sample of a patient's T cells are collected from the blood, then modified to produce special structures called chimeric antigen receptors (CARs) on their surface. While CAR T therapies have proven to be effective in the above products the manufacturing process is complex and very costly leading to extremely high pricing. As an alternative, some companies are pursuing T Cell Receptor (TCR) technology. Unlike CAR T cells that recognize proteins expressed on the surface of a cell, TCRs can recognize tumor-specific proteins on the inside of cells.

We believe the key competitive factors that will affect the development and commercial success of our initial product candidate, ENV 105, if approved, will be other agents that in the future may address resistance mechanisms of therapeutics used for prostate cancer.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state, and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, and export and import of drug products. A new drug must be approved by the FDA through the New Drug Application, or NDA, process before it may be legally marketed in the United States. We, along with any third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our products and product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or FD&C Act, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies in accordance with FDA's Good Laboratory Practice requirements and other applicable regulations;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug for its intended use;
- preparation of and submission to the FDA of an NDA after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, a sponsor must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor, and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- ***Phase 1****:* The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- ***Phase 2****:* The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- ***Phase 3****:* The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy, and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be conducted after initial marketing approval and may be used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

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

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

In addition, during the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical, and other nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling, and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review, The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the filing date to complete a standard review of an NDA for a drug that is a new molecular entity, and of ten months from the date of NDA receipt to complete a standard review of an NDA for a drug that is not a new molecular entity.

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

Before approving an NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the NDA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the NDA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current, or fails to submit a request for approval of a pediatric formulation.

Expedited Development and Review Programs

The FDA offers several expedited development and review programs for qualifying product candidates. For example, the Fast Track program is intended to expedite or facilitate the process for reviewing new products that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a Fast Track designated product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. A Fast Track designated product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

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

A marketing application for a drug submitted to the FDA for approval, including a product candidate with a Fast Track designation and/or Breakthrough Therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review. A product candidate is eligible for priority review if it is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. For new-molecular-entity NDAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date, or with respect to non-new-molecular-entity NDAs, within six months of the NDA receipt date.

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may utilize an accelerated approval pathway upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

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

Exclusivity

The FDA provides periods of non-patent regulatory exclusivity, which provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug for a period of three or five years following the FDA's approval of the NDA. Five years of exclusivity are available to new chemical entities, or NCEs. An NCE is a drug that contains no active moiety that has been approved by the FDA in any other NDA. An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt, including a salt with hydrogen or coordination bonds, or other noncovalent, or not involving the sharing of electron pairs between atoms, derivatives, such as a complex (*i.e.*, formed by the chemical interaction of two compounds), chelate (*i.e.*, a chemical compound), or clathrate (*i.e.*, a polymer framework that traps molecules), of the molecule, responsible for the therapeutic activity of the drug substance. During the exclusivity period, the FDA may not accept for review or approve an Abbreviated New Drug Application, or ANDA, or a 505(b)(2) NDA submitted by another company that contains the previously approved active moiety. An ANDA or 505(b)(2) application, however, may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. Five-year and three-year exclusivity will not delay the submission or approval of a 505(b)(1) NDA; however, an applicant submitting a 505(b)(1) NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy. In addition, under the Generating Antibiotic Incentives Now, or GAIN, Act, the FDA may designate a product as a Qualified Infectious Disease Product, or QIDP. In order to receive this designation, a drug must qualify as an antibiotic or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either (1) an antibiotic or antifungal resistant pathogen, including novel or emerging infectious pathogens, or (2) a so-called ''qualifying pathogen'' found on a list of potentially dangerous, drug-resistant organisms to established and maintained by the FDA. A sponsor must request such designation before submitting a marketing application. Upon approving a marketing application for a QIDP-designated product, the FDA will extend by an additional five years any non-patent marketing exclusivity period awarded. This extension is in addition to any pediatric exclusivity extension awarded, and the extension will be awarded only to a drug first approved on or after the date of enactment of the GAIN Act. The GAIN Act prohibits the grant of an exclusivity extension where the application is a supplement to an application for which an extension is in effect or has expired, is a subsequent application for a specified change to an approved product or is an application for a product that does not meet the definition of QIDP based on the uses for which it is ultimately approved.

Post-approval Requirements

Drug products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

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

The FDA closely regulates the marketing, labeling, advertising, and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity, and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications regarding the label use of their products. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Other Healthcare Laws

In the United States, we are subject to a number of federal and state healthcare regulatory laws that restrict business practices in the healthcare industry. These laws include, but are not limited to, federal and state anti-kickback, false claims, and other healthcare fraud and abuse laws, as follows:

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving, or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for, or recommending the purchase, lease, or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid, or other federal healthcare programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation.

The federal false claims, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U.S. federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Moreover, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

In addition, the civil monetary penalties statute, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program. HIPAA created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by HITECH, and their respective implementing regulations, which impose obligations on "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 requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals including physician assistants and nurse practitioners beginning in 2022, and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMMS ownership and investment interests held by physicians and their immediate family members.

Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; 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, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing information and marketing expenditures or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives.

Violations of any of these laws and other applicable healthcare fraud and abuse laws may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Coverage and Reimbursement

Sales of any pharmaceutical product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. In the United States, no uniform policy exists for coverage and reimbursement for pharmaceutical products among third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. The process for determining whether a third-party payor will provide coverage for a product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved.

Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication, or place products at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service and the level of coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process will often require us to provide scientific and clinical support for the use of our products to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved.

Moreover, as a condition of participating in, and having products covered under, certain federal healthcare programs, such as Medicare and Medicaid, we are subject to federal laws and regulations that require pharmaceutical manufacturers to calculate and report certain price reporting metrics to the government, such as Medicaid Average Manufacturer Price, or AMP, and Best Price, Medicare Average Sales Price, the 340B Ceiling Price, and Non-Federal AMP reported to the Department of Veteran Affairs, and with respect to Medicaid, pay statutory rebates on utilization of manufacturers' products by Medicaid beneficiaries. Compliance with such laws and regulations require significant resources and any findings of non-compliance may have a material adverse effect on our revenues.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In the United States, by way of example, in March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA, among other things, increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer point-of-sale discounts (increased to 70 percent, effective as of January 1, 2019) off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected expanded the types of entities eligible for the 340B drug discount program; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare Innovation at CMMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, administrative, executive, and Congressional legislative challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period from February 15, 2021, through August 15, 2021, for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year, which was temporarily suspended from May 1, 2020 through December 31, 2021, and reduced payments to several types of Medicare providers. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. By way of example, the American Taxpayer Relief Act of 2021, effective January 1, 2024, would eliminate the statutory cap on rebate amounts owed by drug manufacturers under the Medicaid Drug Rebate Program, or MDRP, which is currently capped at 100% of the AMP for a covered outpatient drug. Further, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices.

Individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which drugs and suppliers will be included in their healthcare programs. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including Health Insurance Portability and Accountability Act, or HIPAA, and federal and state consumer protection laws and regulations (*e.g.*, Section 5 of the Federal Trade Commission Act) that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain state and non-U.S. laws, such as the California Consumer Privacy Act, or CCPA, the California Privacy Rights Act, or CPRA, and the General Data Protection Regulation, or GDPR, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to make compliance efforts more challenging, and can result in investigations, proceedings, or actions that lead to significant penalties and restrictions on data processing.

Regulation and Procedures Governing Approval of Medicinal Products in the EU

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to sell any of our product candidates outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by equivalent competent authorities in foreign jurisdictions before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved outside the United States.

The process governing the marketing authorization, or MA, of medicinal products in the EU entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety, quality, and efficacy of the medicinal product for each proposed therapeutic indication.

It also requires the submission to the relevant competent authorities of a marketing authorization application, or MAA and granting of an MA by these authorities before the product can be marketed and sold in the EU.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states, as well as Norway, Liechtenstein and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, or with other applicable regulatory requirements may result in administrative, civil, or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal, or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines, and criminal penalties.

Non-Clinical Studies and Clinical Trials

Similar to the United States, the various phases of non-clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in Directive 2004/10/EC. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU member states govern the system for the approval of clinical trials in the EU.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on International Conference on Harmonization, or ICH, guidelines on GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

Under the applicable regulatory system, an applicant must obtain prior approval from the competent national authority of the EU member states in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a related favorable opinion. The application for authorization of a clinical trial must be accompanied by, among other documents, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation as prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the related implementing national provisions of the individual EU member states, and further detailed in applicable guidance documents. Any substantial changes to the trial protocol or to other information submitted with the clinical trial application must be notified to or approved by the relevant competent national authorities and ethics committees. Medicinal products used in clinical trials must be manufactured in accordance with GMP.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014, or Clinical Trials Regulation, was adopted. The Regulation is anticipated to enter into force on January 31, 2022. The Clinical Trials Regulation will be directly applicable in all of the EU member states, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the EU will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which on-going clinical trials will be governed by the Clinical Trials Regulation will depend on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable, the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the "EU portal;" a single set of documents to be prepared and submitted for the application, as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU member states in which an application for authorization of a clinical trial has been submitted (member states concerned). Part II is assessed separately by each member state concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU member state. However, overall related timelines will be defined by the Clinical Trials Regulation.

Marketing Authorizations

To obtain an MA for a product in the EU, an applicant must submit an MAA either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in the EU member states (decentralized procedure, national procedure, or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

The centralized procedure provides for the grant of a single MA by the European Commission that is valid for all EU member states. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs, and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, autoimmune, and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the EMA's Committee for Medicinal Products for Human Use, or CHMP, is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing MA.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product targeting an unmet medical need is expected to be of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (not including clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU member state in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU member states who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU member state cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralised Procedures—Human (CMDh) for review. The subsequent decision of the European Commission is binding on all EU member states.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU member state to apply for this authorization to be recognized by the competent authorities in other EU member states. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU member states of the MA of a medicinal product by the competent authorities of other EU member states. The holder of a national MA may submit an application to the competent authority of an EU member state requesting that this authority recognize the MA delivered by the competent authority of another EU member state. In principle, an MA has an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU member state in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document, or eCTD, providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU member states may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (in case of centralized procedure) or on the market of the authorizing EU member state within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the United States. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. It permits increased interaction and early dialogue with companies developing promising medicinal products, to optimize their product development plans and speed up their evaluation to help the product reach patients earlier than normal. Product developers that benefit from PRIME designation are potentially eligible for accelerated assessment of their MAA although this is not guaranteed. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a traditional MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

In addition to an MA, various other requirements apply to the manufacturing and placing on the EU market of medicinal products. Manufacture of medicinal products in the EU requires a manufacturing authorization, and import of medicinal products into the EU requires a manufacturing authorization allowing for import. The manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, regulations and guidance. These requirements include compliance with EU GMP standards when manufacturing medicinal products and APIs, including the manufacture of APIs outside of the EU with the intention to import the APIs into the EU. Similarly, the distribution of medicinal products within the EU is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU member states. MA holders, manufacturing and import authorization (MIA) holders, or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU member states' requirements applicable to the manufacturing of medicinal products.

Data and Market Exclusivity

The EU provides opportunities for data and market exclusivity related to MAs. Upon receiving an MA, innovative medicinal products are generally entitled to receive eight years of data exclusivity and ten years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Pediatric Development

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU member states and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate, or SPC, if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Post-Approval Requirements

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion, and sale of medicinal products.

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission, or the competent regulatory authorities of the individual EU member states. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU member states' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with an MA. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

Japanese Drug Regulation

Being a member of the ICH, Japan has pharmaceutical regulations fundamentally similar to those of the United States and the EU. Clinical trials of medicinal products in Japan must be conducted in accordance with Japanese regulations based on ICH guidelines governing GCP. If the sponsor of the clinical trial is not established within Japan, it must appoint an entity within the country to act as its caretaker who should be authorized to act on the sponsor's behalf. The sponsor must take out a clinical trial insurance policy, and, according to the industry agreement, should put in place a common compensation policy for the injuries from the trial. Prior to the commencement of human clinical studies, the sponsor must complete an evaluation of the safety of the investigative product and submit a clinical trial notification and clinical trial protocol to the authorities in advance, upon agreement of the IRB of the participating institutions. When the authorities do not comment on the notification, the sponsor may proceed with the clinical trial. Any substantial changes to the trial protocol or other information submitted must be cleared by the IRB and notified to the authorities. Medicines used in clinical trials must be manufactured in accordance with GMP.

To market a medicinal product in Japan, we must obtain regulatory approval. To obtain regulatory approval of an investigational medicinal product, we must submit a new drug application. If the product is designed for treating certain "difficult diseases" or those whose patient size is limited, we may be able to obtain designation as an orphan drug product if it demonstrates unique therapeutic value. Separately, the latest amendment to the law introduced separate pathways for (i) truly innovative products with a unique mode of action and (ii) those which will satisfy unmet medical needs.

The evaluation of new drug applications is based on an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy. Once the review organization completes its review, the matter is considered by the advisory committee of experts, and the government grants approval upon positive recommendation from the committee.

The volume and quality of the clinical data are key determinants of the approval decision. Clinical trial data generated overseas is accepted as part of the data package consistent with the ICH recommendation. Typically, a limited dose response clinical trial for Japanese subjects is required to ensure that data are extrapolatable for the Japanese population.

Separate from the approval requirement, it is also mandatory to possess a distribution license of an appropriate class for the manufacturer to commercially distribute the product in Japan. Non-Japanese companies who possess only the product approval may designate an appropriate license holder in Japan to commercially distribute the product, rather than distributing it on its own. The license is valid for five years.

Employees and Human Capital Resources

As of September 16, 2024, we had three 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. Our Chief Financial Officer was previously a part-time contractor, although he began serving on a full-time basis upon the effectiveness of our registration statement. All officers and directors of the Company worked approximately 20 hours per week under their appropriate responsibility. Prior to the effectiveness of the registration statement, we had no full-time employees. 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.

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 prospectus, all of our operations are conducted virtually.

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.

MANAGEMENT

Executive Officers, Management, and Directors

We are led by an industry leading senior management team and board of directors with extensive capabilities in immuno-oncology and with a wealth of experience in drug development, commercialization and successful business exits. Collectively, our team possesses a strong record of success, as demonstrated by more than 50 patents held, 12 accepted INDs and approved new drug applications, or NDAs, or biologics license applications, or BLAs, and significant experience at leading life sciences companies including Amgen Inc., Genexine Inc. and Pfizer Inc.

The following table sets forth information regarding our executive officers and directors as of the date of this prospectus.

Name	Age	Position(s)
John S. Yu, M.D.	60	CEO and Chairman of the Board of Directors
Neil Bhowmick, Ph.D.	54	Chief Scientific Officer
Ramachandran Murali. Ph.D.	65	Vice President of Research and Development
Doug Samuelson	65	Chief Financial Officer
Hyun W. Bae, M.D.	55	Director
Rosemary Mazanet M.D., Ph.D.	68	Director Designate*
Hansoo Michael Keyoung, M.D., Ph.D.	50	Director Designate*

* Each director designate will become a member of our board of directors upon effectiveness of this offering.

Executive Officers

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 the field, 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.

Non-Employee Directors

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.

Rosemary Mazanet M.D., Ph.D., Independent Director

Dr. Rosemary Mazanet has agreed to serve on our board of directors as an independent director upon completion of this offering. Since June 2015, Dr. Mazanet has served as the Chair of the Scientific Advisory Board and since September 2017 as Chief Science Officer for Columbia Care, Inc. She is a Director at Oncternal Therapeutics, a Nasdaq-listed company, since January 2021, and private company Angiochem. She has served as Clinical Advisor and interim C-suite management to many companies and funds through her consultancy business, R Mazanet LLC, which she has managed as President since May 2004. Dr. Mazanet also has experience in public equity markets as a Managing Partner at Apelles Investment, LLC from 2007 to 2014, and as the Head of Research at Oracle Partners LP from 1998 to 2004. Prior to her public equity work, Dr. Mazanet worked at Amgen, Inc., where she led Clinical Development teams that conducted successful development programs leading to product approvals. Dr. Mazanet served as a director and member of the audit committee of GTx, Inc., a Nasdaq-listed company, from January 2002 to June 2010 and an independent Director of MasterCell from 2019 to 2020. Both companies were subsequently acquired. Dr. Mazanet has served as a Trustee at the University of Pennsylvania Health System since July 2002, and as the Chair, Executive Advisory Board for the Wharton Leonard Davis Institute since December 2020. Dr. Mazanet holds a B.A. in biology from the University of Virginia, and a Doctor of Medicine degree and a Doctor of Philosophy degree from the University of Pennsylvania. Dr. Mazanet is trained as an internist and oncologist with privileges at the Harvard Hospitals. We believe that Dr. Mazanet is qualified to serve on our board of directors because of her extensive experience managing and advising public and private companies in medical technology fields, her experience in public equity markets, her development team 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 agreed to serve on our board of directors as an independent director upon completion of this offering. 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.

Family Relationships

There are no other 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 currently consists of two members and at the completion of our IPO will consist 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, counseling, and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Director Independence and Diversity

Under the NYSE American Listing Rules independent directors must comprise a majority of our board of directors as a listed company within one year of the listing date. NYSE American Rules also require that boards of directors of five or more members have at least two diverse directors (including at least one woman and at least one member of an underrepresented community) or that boards of directors of four or fewer members have at least one diverse director or, each case, explain why the company has not appointed such diverse directors.

Our board of directors has undertaken a review of the independence and diversity 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 Dr. Bae, Mazanet, and Keyoung, are independent directors and that our board of directors meets the diversity requirements imposed by Nasdaq.

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, in compliance with the NYSE American Listing Rules. 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 intends to adopt a written charter that satisfies the application rules and regulation of the SEC and the NYSE American Listing Rules, which we will post to our website at https://kairospharma.com upon the closing of this offering. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

Upon completion of this offering, our audit committee will consist of Dr. Michael Keyoung, Dr. Hyun W. Bae, and Dr. Rosemary Mazanet, each of whom our board of directors has determined satisfies the independence requirements under the NYSE American Listing Rules and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee will be 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

Upon completion of this offering, our compensation committee will consist of Dr, Rosemary Mazanet, Dr. Hansoo Michael Keyoung, and Dr. Hyun Bae. The chair of our compensation committee will be Dr. Rosemary Mazanet. Our board of directors has determined that each member of our compensation committee is independent under the NYSE American Listing Rules 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

Upon completion of this offering, our nominating and corporate governance committee will consist of Dr. Rosemary Mazanet, Dr. Hyun Bae, and Dr. Michael Keyoung. The chair of our nominating and corporate governance committee will be Dr. Rosemary Mazanet. Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the NYSE American Listing Rules, 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.

Code of Business Conduct and Ethics

In connection with this offering, we intend to adopt 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 will be 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.

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

During the fiscal years ended December 31, 2023 and 2022, Hyun W. Bae, M.D. served on our board of directors as a non-employee director. No compensation was awarded to or earned by or paid to Dr. Bae for the fiscal years ended December 31, 2023 and 2022.

We entered into director agreements with each of our directors in advance of effectiveness of our registration statement. Such agreements will provide for annual cash compensation of $50,000, payable in quarterly installments 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 10,000 restricted stock units ("RSUs") that will vest in substantially equal annual installments over a period of three years. The Director Initial Grant is subject to full acceleration vesting upon the sale of our Company, in accordance with the terms of our 2023 Equity Incentive Plan.

We will reimburse all reasonable out-of-pocket expenses incurred by directors for their attendance at meetings of our board of directors or any committee thereof.

Employee directors will receive no additional compensation for their service as a director.

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 intend to enter into an indemnification agreement with each of our directors and executive officers, which will require us to indemnify them. For more information regarding these agreements, see the section titled "Executive Compensation — Limitations on Liability and Indemnification."

EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2023 and 2022 were Dr. Yu, Dr. Bhowmick, Dr. Murali, and Mr. Samuelson.

Summary Compensation Table

None of our named officers were paid a salary, were granted options, or received any compensation of any type during the fiscal years ended December 31, 2023 and 2022.

Employment Agreements

We have entered into employment agreements with each of our executive officers which will become effective concurrently with the consummation of this initial public offering ("IPO"). At such time, our executive officers will receive compensation on an annual basis in cash, payable in monthly installments, as well as options to purchase common stock subject to achieving certain key performance indicators. 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 will become 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 will also receive 14,000 restricted stock units ("RSUs"), which RSUs 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 the 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. Prior to completion of our IPO, Dr. Yu has received no salary from the Company.

Employment Agreement with Doug Samuelson

We presently have an at will agreement with our Chief Financial Officer, Doug Samuelson, pursuant to which Mr. Samuelson is paid $90.00 per hour, is eligible to receive an annual discretionary bonus, as may be determined by the board of directors, and pursuant to which Mr. Samuelson is eligible to participate in the Company's standard medical, retirement and insurance benefit plans, and is subject to standard non-disclosure and confidentiality provisions.

On September 27, 2023, we entered into an employment agreement with Mr. Samuelson, which employment agreement will become 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 employment agreement will become 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. Prior to completion of our IPO, Dr. Bhowmick received no salary from the Company.

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 will become 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. Prior to completion of our IPO, Dr. Murali received no salary from the Company.

Equity-Based Incentive Awards

Our equity-based incentive awards 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.

We did not grant any equity awards to our named executive officers during the fiscal years ended December 31, 2023 and 2022. Following the completion of this offering, we may grant additional equity awards to our executive officers pursuant to our 2023 Equity Incentive Plan, the terms of which are described below under "—Employee Benefit and Stock Plans—2023 Equity Incentive Plan."

Outstanding Equity Awards as of December 31, 2022 and 2021

In July 2023, we adopted our 2023 Equity Incentive Plan, which reserves 1,650,000 shares of common stock for issuance under the plan. As we only recently adopted our 2023 Equity Incentive Plan, and as we are waiting to complete our initial public offering before we grant any incentive awards, none of our named officers had been granted options, or received any other type of equity compensation, during the fiscal years ended December 31, 2023 and 2022.

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.

Pension Benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during the fiscal years ended December 31, 2023 and 2022.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or earn any benefits under, a non-qualified deferred compensation plan sponsored by us during the fiscal years ended December 31, 2023 and 2022.

Other Compensation and Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, and vision plans, in each case on the same basis as all of our other employees. We pay the premiums for the medical, disability, and accidental death and dismemberment insurance for all of our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers.

Equity Benefit Plans

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants, and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain, and motivate employees, consultants, and directors, and encourages them to devote their best efforts to our business and financial success. As a result, we adopted the 2023 Equity Incentive Plan in July 2023 in advance of this offering. The 2023 Equity Incentive Plan includes the features set forth below.

2023 Equity Incentive Plan

Tax Limitations on Options. Each option will be designated in an award agreement as either an Incentive Stock Option ("ISO") or a Nonstatutory Stock Option ("NSO"). However, notwithstanding such designation, to the extent that the aggregate fair market value of the shares with respect to which ISOs are exercisable for the first time by the participant during any calendar year exceeds $100,000, such options will be treated as NSOs. The fair market value of the shares will be determined as of the time the option with respect to such shares is granted. The administrator will determine the term of each option in its sole discretion; provided, however, that the term will be no more than ten (10) years from the date of grant in the case of ISOs. Moreover, in the event an ISO is granted to a participant who, at the time of grant, owns stock representing more than 10% of the total combined voting power of all classes of stock of the Company, the term of the ISO will be five (5) years from the date of grant or such shorter term as may be provided in the award agreement.

Restricted Stock Unit Awards. Restricted stock units ("RSUs") may be granted at any time and from time to time as determined by the administrator of the 2023 Equity Incentive Plan. Each RSU grant will be evidenced by an award agreement that will specify such other terms and conditions as the administrator, in its sole discretion, will determine in accordance with the terms and conditions of the 2023 Equity Incentive Plan. The administrator, in its discretion, may accelerate the time at which any restrictions will lapse or be removed, subject to the prohibition on acceleration of the timing of distribution of deferred compensation subject to Section 409A of the Code, to the extent applicable to the award. On the date set forth in the award agreement, all unearned RSUs will be forfeited to the Company.

Restricted Stock Awards. Each restricted stock award will be evidenced by an award agreement that will specify the period of restriction, the number of shares granted, and such other terms and conditions as the administrator will determine. During the period of restriction, service providers holding shares of restricted stocks granted hereunder may exercise full voting rights with respect to those shares, unless the administrator determines otherwise in a manner not prohibited by the award agreement. During the period of restriction, service providers holding shares of restricted stocks will be entitled to receive all dividends and other distributions paid with respect to such shares unless otherwise provided in the award agreement. If any such dividends or distributions are paid in shares, the shares will be subject to the same restrictions on transferability and provisions for forfeiture as the shares of restricted stocks with respect to which they were paid. On the date set forth in the award agreement, the restricted stocks for which restrictions have not lapsed will revert to the Company and again will become available for grant under the 2023 Equity Incentive Plan.

Stock Appreciation Rights. Stock appreciation rights will be granted in accordance with stock appreciation rights agreements, in the form adopted by the administrator. The exercise price of stock appreciation rights will be not less than 100% of the fair market value of a share on the date of grant. Each stock appreciation right grant will be evidenced by an award agreement that will specify the exercise price, the number of shares with respect to which the award is granted, the term of the stock appreciation right, the conditions of exercise, and such other terms and conditions as the administrator, in its sole discretion, will determine. Stock appreciation right granted under the 2023 Equity Incentive Plan will expire upon the date determined by the administrator and set forth in the award agreement; provided, however, that the term will be no more than ten (10) years from the date of grant thereof. Upon exercise of a stock appreciation right, a participant will be entitled to receive payment from the Company in an amount determined by multiplying: (i) the difference between the fair market value of a share on the date of exercise over the "stock appreciation right exercise price," as defined under Treasury Regulation Section 1.409A-1(b)(i)(B)(2), i.e., the fair market value of a share on the date of grant of the stock appreciation right; times (ii) the number of shares with respect to which the stock appreciation right is exercised. At the discretion of the administrator, the payment upon stock appreciation right exercise may be in cash, in shares of equivalent value, or in some combination thereof.

Performance Awards. Performance units and performance shares may be granted to service providers at any time and from time to time, as will be determined by the administrator, in its sole discretion. Each performance unit will have an initial value that is established by the administrator on or before the date of grant. Each performance share will have an initial value equal to the fair market value of a share on the date of grant. The administrator will set performance objectives or other vesting provisions. The administrator may set vesting criteria based upon the achievement of Company-wide, business unit, or individual goals (including, but not limited to, continued employment), or any other basis determined by the administrator in its discretion. Each award of performance units/shares will be evidenced by an award agreement that will specify the performance period, and such other terms and conditions as the administrator, in its sole discretion, will determine. After the applicable performance period has ended, the holder of performance units/shares will be entitled to receive a payout of the number of performance units/shares earned by the participant over the performance period, to be determined as a function of the extent to which the corresponding performance objectives or other vesting provisions have been achieved. Payment of earned performance units/shares will be made as soon as practicable after the expiration of the applicable performance period or, if earlier, after the date on which a participant's interest in such performance units/shares is no longer subject to a substantial risk of forfeiture, provided however, that in no event shall such payment be made after the later to occur of (i) December 31 of the year in which such risk of forfeiture lapses or (ii) two and one-half months after such risk of forfeiture lapses. The administrator, in its sole discretion, may pay earned performance units/shares in the form of cash, in shares (which have an aggregate fair market value equal to the value of the earned performance units/shares at the close of the applicable performance period) or in a combination thereof. On the date set forth in the award agreement, all unearned or unvested performance units/shares will be forfeited to the Company, and again will be available for grant under the Plan.

Other Stock Awards. The administrator may grant other awards based in whole or in part by reference to our common stock. The administrator will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

Adjustments. In the event that any dividend or other distribution (whether in the form of cash, shares, other securities, or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, or exchange of shares or other securities of the Company, or other change in the corporate structure of the Company affecting the shares occurs, the administrator, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under the 2023 Equity Incentive Plan, will adjust the number and class of shares that may be delivered under the 2023 Equity Incentive Plan and/or the number, class, and price of shares covered by each outstanding award, and the numerical share limits set forth thereof.

Dissolution or Liquidation. In the event of the proposed dissolution or liquidation of the Company, any corporate separation or division, including, but not limited to, a split-up, a split-off or a spin-off; a reverse merger in which the Company is the surviving entity, but the shares of Company stock outstanding immediately preceding the merger are converted by virtue of the merger into other property, whether in the form of securities, cash or otherwise; or the transfer of more than fifty percent (50%) of the then outstanding voting stock of the Company to another person or entity, the administrator will notify each participant as soon as practicable prior to the effective date of such proposed transaction. The Company, to the extent permitted by applicable law but otherwise in its sole discretion may provide for: (i) the continuation awards by the Company (if the Company is surviving entity or its parent; (ii) the assumption of the 2023 Equity Incentive Plan and such outstanding awards by the surviving entity or its parent; (iii) the substitution by the surviving entity or its parent of rights with substantially the same terms for such outstanding awards; or (iv) the cancellation of such outstanding rights without payment of any consideration provided that in the case of this clause (iv), the administrator will provide notice of its intention to cancel award and offer a reasonable opportunity to exercise vested awards.

Change in Control. In the event of a merger or change in control, as defined in the 2023 Equity Incentive Plan, each outstanding award will be treated as the administrator determines, including, without limitation, that each award will be assumed or an equivalent option or right substituted by the successor corporation or a parent or subsidiary of the successor corporation. The administrator will not be required to treat all awards similarly in the transaction.

Plan Amendment or Termination. The administrator may at any time amend, alter, suspend, or terminate the 2023 Equity Incentive Plan. The Company will obtain stockholder approval to any amendment to the 2023 Equity Incentive Plan to the extent necessary or desirable to comply with applicable rules and regulations. No amendment, alteration, suspension, or termination of the 2023 Equity Incentive Plan will impair the rights of any participant, unless mutually agreed otherwise between the participant and the administrator, which agreement must be in writing and signed by the participant and the Company. Termination of the 2023 Equity Incentive Plan will not affect the administrator's ability to exercise the powers granted to it thereunder with respect to awards granted under the 2023 Equity Incentive Plan prior to the date of such termination.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions since January 1, 2021 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, 2023, 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, shareholders 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

Prior to effectiveness of this offering, we intend to adopt a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock, and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the approval or ratification of our board of directors or our audit committee. 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.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock as of the date of this prospectus 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 before the offering is based on 10,562,640 shares of our common stock outstanding as of September 16, 2024.

Applicable percentage ownership after the offering is based on shares of common stock outstanding immediately after the closing of this offering, after giving effect to the issuance of 369,248 shares of common stock upon conversion of convertible notes payable and notes payable - officers, conversion of amounts due to related parties and an officer into 47,549 shares of common stock and 312,500 shares of common stock upon conversion of certain accounts payable, in connection with the closing of this offering. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to options held by the person that are currently exercisable, or exercisable within 60 days of the date of this prospectus. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is 2355 Westwood Blvd. #139, Los Angeles, California 90064.

		Percentage of Shares Beneficially Owned	
Name of Beneficial Owner	**Number of Shares Beneficially Owned (#)**	**Before Offering (%)**	**After Offering (%)***
Greater than 5% Holders:			
Technomedics Management and Systems, Inc.[(1)]	1,173,572	11.1	9.1
Belmet Therapeutics, LLC[(2)]	997,750	9.4	7.8
Directors and Named Executive Officers:			
John S. Yu, M.D.[(3)]	5,326,940	50.3	41.5
Ramachandran Murali, Ph.D.	132,857	1.3	1.0
Neil Bhowmick, Ph.D.[(4)]	1,124,844	10.6	8.8
Douglas Samuelson[(5)]	52,465	*	*
Hyun W. Bae, M.D	44,286	**	**
Rosemary Mazanet, M.D.	-	-	-
Hansoo Michael Keyoung, M.D.	-	-	-
All directors and executive officers as a group (7 persons)	6,681,392	62.6	52.0

*Calculated assuming 12,841,937 shares outstanding after the offering, assuming 1,550,000 shares sold in the offering not including the underwriters' overallotment option.
** 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) Judith Buchmiller is the beneficial owner of, and exercises voting control and investment power over, all shares held in the name of Belmet Therapeutics, LLC.
(3) Consists of (i) 5,316,572 shares of common stock and (i) 10,368 shares of common stock underlying a promissory note, which note will convert into common stock at a $4.00 per share conversion price upon completion of the IPO.
(4) Consists of (i) 1,116,000 shares of common stock and (ii) 8,844 shares of common stock underlying certain promissory notes which will convert into common stock at a $4.00 per share conversion price upon completion of the IPO.
(5) Consists of a total of $178,950 of accounts payable and notes payable which will convert into common stock, at a conversion price of $4.00 per share, following completion of the IPO.

DESCRIPTION OF CAPITAL STOCK

General

The following description of our capital stock and certain provisions of our certificate of incorporation and bylaws are summaries and are qualified by reference to the certificate of incorporation and the bylaws. Copies of these documents have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part.

Our authorized capital stock consists of 100,000,000 shares of common stock, par value $0.001 per share and 20,000,000 shares of preferred stock, par value $0.001 per share.

As of the date of this prospectus, prior to giving effect to the issuance of 1,550,000 shares of common stock being sold in this offering and 369,248 shares of common stock issuable upon conversion of convertible notes and notes payable – officers, 47,549 shares of common stock issuable upon conversion of certain accounts payable to related parties and an officer, and 312,500 shares of common stock issuable upon conversion of certain accounts payable upon effectiveness of this offering, there were 10,562,640 shares of common stock outstanding and held of record by 27 stockholders.

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share owned on all matters voted upon by shareholders, and a majority vote is required for all actions to be taken by shareholders.

Economic Rights

Except as otherwise expressly provided in our certificate of incorporation or required by applicable law, all shares of our common stock will have the same rights and privileges and rank equally, share ratably and be identical in all respects for all matters, including those described below.

Dividends. Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine. See the section titled “Dividend Policy” for further information.

Liquidation Rights. On our liquidation, dissolution, or winding-up, the holders of our stock will be entitled to share equally, identically, and ratably in all assets remaining after the payment of any liabilities, liquidation preferences, and accrued or declared but unpaid dividends, if any, with respect to any outstanding preferred stock, unless a different treatment is approved by the affirmative vote of the holders of a majority of the outstanding shares of such affected class, voting separately as a class.

No Preemptive or Similar Rights

The holders of shares of our common stock are not entitled to preemptive rights, and are not subject to conversion, redemption, or sinking fund provisions.

Fully Paid and Non-Assessable

In connection with this offering, our legal counsel will opine that the shares of our common stock to be issued under this offering will be fully paid and non-assessable.

Preferred Stock

Under our certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 20,000,000 shares of preferred stock, par value $0.001 per share, in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of our common stock. We have no current plans to issue any shares of preferred stock.

Registration Rights

Upon the closing of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, certain holders of shares of our common stock, including those shares of our common stock that will be issued upon the conversion of convertible notes in connection with this offering, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our investors' rights and lock-up agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback, and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will expire no later than three years after the closing of this offering.

Demand Registration Rights

Upon the closing of this offering, holders of an aggregate of 369,248 shares of our common stock, following conversion of convertible notes, will be entitled to certain demand registration rights. At any time beginning 180 days after the closing of this offering, the holders of a majority of these shares may request that we register all or a portion of their shares. We are not required to effect more than registration statements which are declared or ordered effective. Such request for registration must cover shares with an anticipated aggregate offering price of at least $5 million. With certain exceptions, we are not required to effect the filing of a registration statement during the period starting with the date of the filing of, and ending on a date 180 days following the effective date of the registration statement for this offering.

Piggyback Registration Rights

In connection with this offering, the holders of an aggregate of 484,375 shares of our common stock, consisting of 369,248 shares of common stock issuable upon conversion of convertible notes and exercise of warrants to purchase 150,000 shares of common stock, will be entitled to piggy back registration rights, and the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering. After this offering, in the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the holders of these shares will be entitled to certain piggyback registration rights allowing the holder to include their shares in such registration, subject to certain marketing and other limitations.

Anti-Takeover Provisions

The provisions of Delaware law, our certificate of incorporation, and our bylaws, which are summarized below, may have the effect of delaying, deferring, or discouraging another person from acquiring control of our company. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Certificate of Incorporation and Bylaws

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock will be able to elect all of our directors. Our certificate of incorporation and our bylaws provide for stockholder actions at a duly called meeting of stockholders or by written consent, subject to relevant proxy rules. A special meeting of stockholders may be called by a majority of our board of directors, the chair of our board of directors, or our chief executive officer or president. Our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors.

The authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

When we have a class of voting stock that is either listed on a national securities exchange or held of record by more than 2,000 stockholders, we will be subject to Section 203 of the DGCL which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, subject to certain exceptions.

Choice of Forum

Our certificate of incorporation provides that unless we consent in writing to the selection of an alternative forum, and except for any actions brought under the Securities Act or the Exchange Act (which actions are specifically excluded from the exclusive jurisdiction clause in our certificate of incorporation), the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, other employees to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws; (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder); and (v) any action asserting a claim against us governed by the internal affairs doctrine.

Note that 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.

For the avoidance of doubt, these provisions are intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, our certificate of incorporation provides that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

Limitations on Liability and Indemnification

The DGCL authorizes corporations to limit or eliminate the personal liability of directors of corporations and their stockholders for monetary damages for breaches of directors' fiduciary duties, subject to certain exceptions. The Company's certificate of incorporation includes a provision that eliminates the personal liability of directors for damages for any breach of fiduciary duty as a director where, in civil proceedings, the person acted in good faith and in a manner that person reasonably believed to be in or not opposed to the best interests of the Company or, in criminal proceedings, where the person had no reasonable cause to believe that his or her conduct was unlawful.

The Company's bylaws provide that the Company must indemnify and advance expenses to its directors and officers to the fullest extent authorized by the DGCL. The Company also is expressly authorized to carry directors' and officers' liability insurance providing indemnification for its directors, officers, and certain employees for some liabilities. The Company believes that these indemnification and advancement provisions and insurance are useful to attract and retain qualified directors and executive officers.

The limitation of liability, advancement and indemnification provisions in the certificate of incorporation and bylaws may discourage stockholders from bringing lawsuit against directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit the Company and its stockholders. In addition, your investment may be adversely affected to the extent the Company pays the costs of settlement and damage awards against directors and officer pursuant to these indemnification provisions.

There is currently no pending material litigation or proceeding involving any of the Company's directors, officers, or employees for which indemnification is sought.

Corporate Opportunities

The certificate of incorporation provides for the renouncement by the Company of any interest or expectancy of the Company in, or being offered an opportunity to participate in any matter, transaction, or interest that is presented to, or acquired, created, or developed by, or which otherwise comes into possession of, any director of the Company who is not an employee or officer of the Company or any of its subsidiaries, unless such matter, transaction, or interest is presenting to, or acquired, created, or developed by, or otherwise comes into the possession of a director of the Company expressly and solely in that director's capacity as a director of the Company.

Dissenters' Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, the Company's stockholders will have appraisal rights in connection with a merger or consolidation of the Company. Pursuant to the DGCL, stockholders who properly request and perfect appraisal rights in connection with such merger or consolidation will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery.

Stockholders' Derivative Actions

Under the DGCL, any of the Company's stockholders may bring an action in the Company's name to procure a judgment in the Company's favor, also known as a derivative action, provided that the stockholder bringing the action is a holder of the Company's shares at the time of the transaction to which the action relates or such stockholder's stock thereafter devolved by operation of law.

Exchange Listing

Our common stock is not currently listed on any securities exchange. Our common stock has been approved for listing on the NYSE American LLC, or NYSE American, under the symbol "KAPA."

Transfer Agent and Registrar

The transfer agent for our capital stock is VStock Transfer LLC, located in Woodmere, NY. The phone number of our transfer agent is (212) 828-8436.

SHARES ELIGIBLE FOR FUTURE SALE

Before the closing of this offering, there was no public market for our common stock. Future sales of substantial amounts of our common stock, including shares issued on the exercise of outstanding options, in the public market after this offering, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital.

Based on 10,562,640 shares outstanding as of September 16, 2024, upon the closing of this offering, a total of 12,841,937 shares of common stock will be outstanding (and 13,074,437 shares of common stock outstanding if the underwriters exercise their overallotment option), assuming the automatic conversion upon the closing of this offering of all convertible notes and notes payable – officers outstanding into 369,248 shares of our common stock, conversion of amounts due to related parties and one of our officers into 47,549 shares of common stock, and conversion of $750,000 in accounts payable into 312,500 shares of common stock. Of these shares, all of the common stock sold in this offering by us, plus any shares sold by us on exercise of the underwriters' option to purchase additional common stock, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by "affiliates," as that term is defined in Rule 144 under the Securities Act, or Rule 144.

The remaining shares of common stock, as well as, upon issuance, the shares of common stock subject to stock options, will be "restricted securities," as that term is defined in Rule 144. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below.

Subject to the lock-up agreements described below and the provisions of Rule 144 or Rule 701 under the Securities Act, as well as our insider trading policy, these restricted securities will be available for sale in the public market after the date of this prospectus.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates, or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares of common stock from us; or

- the average weekly trading volume of our common stock on NYSE American during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 of the Securities Act (Rule 701) generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below.

Form S-8 Registration Statements

Following the effectiveness of our registration statement, we intend to file with the SEC a registration statement on Form S-8 under the Securities Act to register the offer and sale of shares of our common stock that are issuable under our equity incentive plan. This registration statement will become effective immediately upon filing. Shares covered by the registration statement on Form S-8 will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below, and Rule 144 limitations applicable to affiliates.

Lock-up Arrangements

We, and all of our directors, executive officers, and the holders of substantially all of our common stock and securities exercisable for or convertible into our common stock outstanding immediately on the closing of this offering, have agreed with the underwriters that, until 360 days for officers and directors and 180 days for all other holders after the date of the underwriting agreement related to this offering, we and they will not (and will not cause or direct any affiliate to), without the prior written consent of the representatives of the underwriters, subject to certain exceptions, directly or indirectly, offer, pledge, sell, contract to sell, assign, transfer, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right, or warrant to purchase, lend or otherwise transfer or dispose of, or announce the intention to otherwise dispose of, any of our shares of common stock, or any securities convertible into or exercisable or exchangeable for shares of our common stock, or enter into, or announce the intention to enter into, any hedging, swap, or similar agreement or arrangement that transfers, is designed to transfer or reasonably could be expected to transfer, in whole or in part, directly or indirectly, the economic consequence of ownership of the securities, whether any such swap or transaction is to be settled by delivery of our common stock or other securities, in cash or otherwise. These agreements are described in the section entitled "Underwriting." The representatives of the underwriters, however, may, in their sole discretion, release any of the securities subject to these lock-up agreements at any time.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including the amended and restated investors' rights agreement, our standard form of option agreement and our standard form of restricted stock agreement, that contain market stand-off provisions or incorporate market stand-off provisions from our equity incentive plan imposing restrictions on the ability of such security holders to offer, sell, or transfer our equity securities for a period of 180 days following the date of this prospectus.

Registration Rights

Upon the closing of this offering, subject to the lock-up provisions set forth above and pursuant to our amended and restated investors' rights agreement, the holders of shares of our common stock, or their transferees, will be entitled to certain rights with respect to the registration of the offer and sale of their shares under the Securities Act, subject to the terms of the lock-up agreements described under the section titled "—Lock-up Arrangements" above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately on the effectiveness of the registration. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a summary of certain material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local, or foreign tax laws, or any other U.S. federal tax laws. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the IRS, all as in effect on the date of this prospectus. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a non-U.S. holder in light of such non-U.S. holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to non-U.S. holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other pass-through entities (and investors therein);
- "controlled foreign corporations;"
- "passive foreign investment companies;"
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers, or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons who acquire our common stock through the exercise of an option or otherwise as compensation;
- qualified foreign pension funds as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons subject to the alternative minimum tax;
- persons subject to special tax accounting rules under Section 451(b) of the Code;
- persons that own or have owned, actually or constructively, more than 5% of our common stock;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

THIS DISCUSSION IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING, AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.

Definition of Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is not a "U.S. person" or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;

- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (i) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust, or (ii) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

Distributions on Our Common Stock

As described in the section titled "Dividend Policy," we do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. However, if we distribute cash or other property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder's tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under "–Gain on Disposition of Our Common Stock" below.

Subject to the discussion below regarding effectively connected income, backup withholding and FATCA (as defined below), dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our withholding agent with a valid IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying such holder's qualification for the reduced rate. This certification must be provided to us or our withholding agent before the payment of dividends and must be updated periodically. In the case of a non-U.S. holder that is an entity, Treasury Regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of the tax treaty, dividends will be treated as paid to the entity or to those holding an interest in the entity. If the non-U.S. holder holds our common stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our withholding agent, either directly or through other intermediaries.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder's U.S. trade or business (and are attributable to such holder's permanent establishment or fixed base in the United States if required by an applicable tax treaty), the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent.

However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and FATCA (as defined below), a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- we are or become a United States real property holding corporation, or a USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock, and our common stock is not regularly traded on an established securities market during the calendar year in which the sale or other disposition occurs.

Determining whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We believe that we are not currently and we do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), on gain realized upon the sale or other taxable disposition of our common stock which may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. If we are or become a United States real property holding corporation during the period described in the third bullet point above and our common stock is not regularly traded for purposes of the relevant rules, gain arising from the sale or other taxable disposition of our common stock by a non-U.S. holder will generally be subject to U.S. federal income tax in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required because the distributions were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-8ECI, or certain other requirements are met, and if the payor does not have actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

Withholding on Payment to Certain Foreign Accounts or Entities

Sections 1471 through 1474 of the Code (commonly referred to as FATCA), impose a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our common stock and would have applied also to payments of gross proceeds from the sale or other disposition of our common stock. The U.S. Treasury Department has released proposed regulations under FATCA providing for the elimination of the federal withholding tax of 30% applicable to gross proceeds of a sale or other disposition of our common stock. Under these proposed Treasury Regulations (which may be relied upon by taxpayers prior to finalization), FATCA will not apply to gross proceeds from sales or other dispositions of our common stock.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

UNDERWRITING

In connection with this offering, we entered into an underwriting agreement with Boustead Securities, LLC to serve as lead book-running manager of the offering and as representative of the several underwriters (if any) named below. Subject to the terms and conditions of the underwriting agreement, each underwriter will severally agree to purchase the number of shares of common stock set forth opposite its name below at the initial public offering price less underwriting discounts and commissions.

Underwriter	Number of Shares of Common Stock
Boustead Securities, LLC	-
Sutter Securities, Inc.	739,410
EF Hutton LLC	810,590
Total	1,550,000

Subject to the terms and conditions set forth under the underwriting agreement, the underwriters have agreed to purchase 1,550,000 shares of common stock offered by this prospectus (other than those covered by the over-allotment option described below, if any are purchased).

The underwriters are offering the shares of common stock subject to various conditions and may reject all or part of any order. The representative of the underwriters has advised us that the underwriters propose initially to offer the shares of common stock to the public at the public offering price set forth on the cover page of this prospectus and to dealers at a price less a concession not in excess of $0.16 per share of common stock. After the shares of common stock are released for sale to the public, the representative may change the offering price, the concession, and other selling terms at various times.

Discounts and Commissions

The following table provides information regarding the amount of the discounts and commissions to be paid to the underwriters by us, before expenses. The information assumes either no exercise or full exercise of the over-allotment option we granted to the representative of the underwriters:

	Per Share of Common Stock	Total Without Over-Allotment Option	Total With Over-Allotment Option
Initial public offering price	$ 4.00	$ 6,200,000	$ 7,130,000
Underwriting discounts and commission (7%)	$ 0.28	$ 434,000	499,100
Non-accountable expense allowance (1%)	$ 0.04	$ 62,000	71,300
Proceeds, before expenses, to us	$ 3.68	$ 5,704,000	6,559,600

We have agreed to pay the representative the reasonable out-of-pocket expenses incurred by the representative in connection with this offering up to $280,000. The representative's reimbursable out-of-pocket expenses include: (i) reasonable fees of representative's legal counsel up to $125,000, (ii) due diligence and other expenses incurred prior to completion of this offering up to $75,000, (iii) road show, travel, platform on-boarding fees, and other reasonable out-of-pocket accountable expenses up to $75,000, and (iv) $5,000 for background check on our officers, directors and major shareholders. As of the date of this prospectus, we have paid the representative advances of $50,000 for its anticipated out-of-pocket costs. Such advance payments will be returned to us to the extent such out-of-pocket expenses are not actually incurred in accordance with FINRA Rule 5110(g)(4)(A).

We estimate that our total expenses of the offering, excluding the estimated underwriting discounts and commissions and excluding the non-accountable expense allowance, will be approximately $700,000.

Representative's Warrants

We have also agreed to issue to the representative of the underwriters warrants to purchase a number of shares of common stock equal to an aggregate of 7% of the aggregate number of the shares sold in this offering. The warrants will be exercisable on a cashless basis at an exercise price equal to 120% of the offering price of the shares sold in this offering. The warrants are exercisable commencing six months after the date of effectiveness of the registration statement of which this prospectus forms a part, and the warrants will be exercisable for a period of five years from the effective date of the registration statement of which this prospectus forms a part. We have agreed to a one-time demand registration of the shares of common stock underlying the underwriter's warrants for a period of five years from the effective date of the registration statement. The underwriter's warrants also provide for immediate "piggyback" registration rights with respect to the underlying shares of common stock during the five-year period commencing from the effective date of the registration statement related to this offering. Such piggyback rights shall expire on a date which shall be five years from the date of commencement of sales of the share offered hereby. The warrants are not redeemable by us. The warrants and the shares of common stock issuable upon exercise of the warrants have been included on the registration statement of which this prospectus forms a part. Pursuant to applicable FINRA rules, and in particular Rule 5110, the warrants (and underlying shares) issued to the underwriters may not be sold, transferred, assigned, pledged, or hypothecated, or the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective disposition of the securities by any person for a period of 180 days after the effective date of the registration statement related to this offering; provided, however, that the warrants (and the underlying shares) may be transferred to the underwriters' officers, partners, registered persons or affiliates as long as the warrants (and the underlying shares) remain subject to the lockup.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

Right of First Refusal

We have agreed to provide the representative of the underwriters the right of first refusal for one year from the date of commencement of sales of this public offering to act as financial advisor or to act as joint financial advisor on at least equal economic terms on any public or private financing (debt or equity), merger, business combination, recapitalization or sale of some or all of the equity or assets of our company.

Company and Shareholder Lock-Ups

We have agreed to a 12-month "lock-up" from the closing of this offering, during which, without the prior written consent of Boustead Securities, LLC, we will not issue, sell or register with the SEC (other than on Form S-8 or on any successor form) with respect to any of our equity securities (or any securities convertible into, exercisable for or exchangeable for any of our equity securities), except for (i) the issuance of the shares of common stock offered pursuant to this prospectus; and (ii) the issuance of shares of common stock pursuant to our existing equity incentive or bonus plan as described in the registration statement of which this prospectus forms a part.

Our executive officers, directors and certain of our significant stockholders have also agreed to a 12-month "lock-up," during which, without the prior written consent of Boustead Securities, LLC, they will not, directly or indirectly, (i) offer, pledge, assign, encumber, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock, owned either of record or beneficially (as defined in the Exchange Act) by any signatory of the lock-up agreement on the date of the prospectus or thereafter acquired; (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common stock or any securities convertible into or exercisable or exchangeable for common stock, whether any such transaction described in clauses (i) or (ii) above is to be settled by delivery of common stock or such other securities, in cash or otherwise, or publicly announce an intention to do any of the foregoing; and (iii) make any demand for or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock. The foregoing shall not apply to (i) common stock to be transferred as a gift or gifts (provided that (a) any donee shall execute and deliver to Boustead Securities, LLC, acting on behalf of the underwriters, not later than one business day prior to such transfer, a lock-up agreement to Boustead Securities, LLC and (b) if the lock-up signatory is required to file a report under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock or beneficially owned shares or any securities convertible into or exercisable or exchangeable for common stock or beneficially owned shares during the 15-month "lock-up," the lock-up signatory shall include a statement in such report to the effect that such transfer is being made as a gift), and (ii) the sale of the shares of common stock to be sold pursuant to this prospectus.

Rules of the SEC may limit the ability of the underwriters to bid for or purchase shares of our common stock before the distribution of the shares is completed. However, the underwriters may engage in the following activities in accordance with the rules:

- Stabilizing transactions — the representative may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, so long as stabilizing bids do not exceed a specified maximum.

- Over-allotments and syndicate covering transactions — the underwriters may sell more shares of common stock in connection with this offering than the number of shares that they have committed to purchase. This over-allotment creates a short position for the underwriters. This short sales position may involve either "covered" short sales or "naked" short sales. Covered short sales are short sales made in an amount not greater than the underwriter's over-allotment option to purchase additional shares in this offering described above. The underwriters may close out any covered short position either by exercising their over-allotment option or by purchasing shares in the open market. To determine how they will close the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market, as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are short sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that, in the open market after pricing, there may be downward pressure on the price of the shares that could adversely affect investors who purchase shares in this offering.

- Penalty bids — if the representative purchases shares of common stock in the open market in a stabilizing transaction or syndicate covering transaction, it may reclaim a selling concession from the underwriters and selling group members who sold those shares of common stock as part of this offering.

- Passive market making — market makers in the common stock who are underwriters or prospective underwriters may make bids for or purchases of shares of common stock, subject to limitations, until the time, if ever, at which a stabilizing bid is made.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales or to stabilize the market price of our common stock may have the effect of raising or maintaining the market price of our common stock or preventing or mitigating a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the common stock if it discourages resales of our shares of common stock.

Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may occur on NYSE American or otherwise. If such transactions are commenced, they may be discontinued without notice at any time.

Prior Relationship with Boustead Securities, LLC

In June and September 2022, we completed a $450,000 convertible note offering and a $225,000 convertible note offering, respectively, to certain accredited investors, which notes are convertible into shares of common stock (the "Conversion Shares") at a conversion price equal to 60% of the per share of common stock sold in this offering. The convertible note offering was completed pursuant to an exemption from registration under Rule 506(b) of the Securities Act. Boustead Securities, LLC acted as placement agent in each of the June and September 2022 private placements and received $86,893 and $19,315 cash compensation, respectively, and five-year warrants to purchase shares of common stock equal to 7.0% of the number of the Conversion Shares at an exercise price equal to the conversion price.

The warrants received in connection with the June and September 2022 private placements (the "Private Placement Warrants") (and underlying shares) will not be exercisable or convertible more than five years from the commencement of this public offering. Pursuant to applicable FINRA rules and, in particular, Rule 5110(e)(1), the Private Placement Warrants (and underlying shares) may not be sold, transferred, assigned, pledged or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities for a period of 180 days beginning on the date of commencement of sales of this public offering; provided, however, the Private Placement Warrants (and underlying shares) may be transferred to the underwriter's officers, partners, registered persons or affiliates as long as the warrants remain subject to the lock-up restriction above.

Electronic Delivery of Prospectus: A prospectus in electronic format may be delivered to potential investors by one or more of the underwriters participating in this offering. The prospectus in electronic format will be identical to the paper version of such prospectus. Other than the prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part.

Determination of Offering Price

Prior to the offering there has not been a public market for our shares of common stock. As a result, the public offering price for our shares of common stock has been determined by negotiations between us and the representative of the underwriters. Among the factors to be considered in these negotiations were the prevailing market conditions, our financial information, market valuations of other companies that we and the representative believe to be comparable to us, estimates of our business potential, the present states of our development and other factors deemed relevant.

We offer no assurance that the public offering price will correspond to the price at which the shares of common stock will trade in the public market subsequent to the offering or that an active trading market for the shares of common stock will develop and continue after the offering.

Selling Restrictions

Canada. The common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

European Economic Area. In relation to each Member State of the European Economic Area (each, a Relevant State), no shares of common stock have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares of common stock which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares of common stock may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares of common stock shall require our company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares of common stock or to whom any offer is made will be deemed to have represented, acknowledged, and agreed to and with each of the underwriters and our company that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares of common stock being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged, and agreed that the shares of common stock acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares of common stock to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "offer to the public" in relation to the shares of common stock in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of common stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of common stock, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

***United Kingdom*.** No shares of common stock have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares of common stock which has been approved by the Financial Conduct Authority, except that the shares of common stock may be offered to the public in the United Kingdom at any time:

- to any legal entity which is a qualified investor as defined under Article 2 of the U.K. Prospectus Regulation;
- to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the U.K. Prospectus Regulation), subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Section 86 of the FSMA,

provided that no such offer of the shares of common stock shall require our company or any underwriter to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the U.K. Prospectus Regulation. For the purposes of this provision, the expression an "offer to the public" in relation to the shares of common stock in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of common stock to be offered so as to enable an investor to decide to purchase or subscribe for any shares of common stock and the expression "U.K. Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018. In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the U.K. Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or the "Order," and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as relevant persons). In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons. Any person in the United Kingdom who is not a relevant person must not act on or rely upon this document or any of its contents.

***Switzerland*.** The securities will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to article 652a or 1156 of the Swiss Federal Code of Obligations.

***Israel*.** In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728–1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728–1968, including, inter alia, if: (i) the offer is made, distributed, or directed to not more than 35 investors, subject to certain conditions (Addressed Investors); or (ii) the offer is made, distributed, or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728–1968, subject to certain conditions (Qualified Investors). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. Our company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728–1968. We have not and will not distribute this prospectus or make, distribute, or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728–1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728–1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728–1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728–1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728–1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728–1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on our behalf, other than offers made by the underwriters and their respective affiliates, with a view to the final placement of the securities as contemplated in this document. Accordingly, no purchaser of the shares, other than the underwriters, is authorized to make any further offer of shares on our behalf or on behalf of the underwriters.

LEGAL MATTERS

The validity of the securities being offered by this prospectus will be passed upon for us by Dorsey & Whitney LLP, New York, New York. Olshan Frome Wolosky LLP, New York, New York, is acting as counsel for the underwriters.

EXPERTS

The audited consolidated financial statements of Kairos Pharma, Ltd. as of December 31, 2023, and 2022 and for each of the years then ended included in this prospectus have been so included in reliance on the report of Marcum LLP, an independent registered public accounting firm, which includes an explanatory paragraph as to our company's ability to continue as a going concern, given upon their authority as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

On the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements, and other information with the SEC. These reports, proxy statements, and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above.

We also maintain a website at https://kairospharma.com. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference.

Kairos Pharma, Ltd.

Index to the Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Kairos Pharma, Ltd. and Subsidiary (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, shareholders' deficit and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying 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 a significant working capital deficiency, 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 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

Marcum LLP

We have served as the Company's auditor since 2021.

Los Angeles, California
April 30, 2024

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

	December 31,		Pro Forma December 31,
	2022	2023	2023
ASSETS			
Current Assets			
Cash	$ 437	$ 93	$ 93
Prepaid expenses	-	8	8
Total Current Assets	437	101	101
Deferred offering costs	57	482	482
Intangible assets, net	542	382	382
Total Other Assets	599	864	864
TOTAL ASSETS	$ 1,036	$ 965	$ 965
LIABILITIES AND SHAREHOLDERS' DEFICIT			
Current Liabilities			
Accounts payable and accrued expenses	$ 1,629	$ 2,401	$ 1,591
Due to related parties	4	4	-
Total Current Liabilities	1,633	2,405	1,591
Convertible notes payable, net of debt discount of $93 and $105 at December 31, 2022 and 2023, respectively	582	638	-
Total Liabilities	2,215	3,043	1,591
Shareholders' Deficit			
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; 10,334,357 and 10,562,640 shares issued and outstanding, respectively; 11,211,179 shares issued and outstanding pro forma (unaudited)	10	11	11
Additional paid-in capital	3,211	4,123	5,680
Accumulated deficit	(4,400)	(6,212)	(6,317)
Total Shareholders' Deficit	(1,179)	(2,078)	(626)
TOTAL LIABILITIES AND SHAREHOLDERS' DEFICIT	$ 1,036	$ 965	$ 965

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,	
	2022	**2023**
Revenues	$ -	$ -
Operating expenses:		
Research and development	87	82
General and administrative	484	1,632
Total operating expenses	571	1,714
Loss from operations	(571)	(1,714)
Other expenses:		
Interest expense	(51)	(42)
Debt discount amortization	(408)	(56)
Financing costs	(20)	-
Total other expenses	(479)	(98)
NET LOSS	$ (1,050)	$ (1,812)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.10)	$ (0.17)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING BASIC AND DILUTED	10,236,764	10,382,515
PRO FORMA BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.10)	$ (0.16)
PRO FORMA WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING BASIC AND DILUTED	10,839,452	11,031,054

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

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

	Common Stock		Common Stock to be Issued		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance, December 31, 2021	8,055,575	$ 8	2,124,000	$ 2	$ 2,173	$ (3,350)	$ (1,167)
Shares issued from common stock to be issued	2,124,000	2	(2,124,000)	(2)	-	-	-
Shares issued upon conversion of convertible notes payable and accrued interest	154,782	-	-	-	648	-	648
Fair value of stock warrant issued in connection with convertible note payable	-	-	-	-	390	-	390
Net loss	-	-	-	-	-	(1,050)	(1,050)
Balance, December 31, 2022	10,334,357	$ 10	-	$ -	$ 3,211	$ (4,400)	$ (1,179)
Fair value of shares issued in connection with shareholder dispute	228,283	1	-	-	912	-	913
Net loss	-	-	-	-	-	(1,812)	(1,812)
Balance, December 31, 2023	10,562,640	$ 11	-	$ -	$ 4,123	$ (6,212)	$ (2,078)

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,	
	2022	**2023**
Cash Flows from Operating Activities		
Net loss	$ (1,050)	$ (1,812)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Amortization expense	160	160
Amortization of debt discount	408	56
Fair value of common stock issued in connection with shareholder dispute	-	913
Changes in operating assets and liabilities:		
(Increase) Decrease in:		
Prepaid expenses	-	(8)
(Decrease) Increase in:		
Accounts payable and accrued expenses	129	772
Net cash provided by (used in) operating activities	(353)	81
Cash Flows from Financing Activities		
Proceeds from convertible notes payable	925	-
Repayment of note payable	(30)	-
Repayment of advance from related party	(10)	-
Payment of debt isuance costs	(111)	-
Payment of deferred offering costs	(57)	(425)
Net cash provided by (used in) financing activities	717	(425)
Net increase (decrease) in cash	364	(344)
Cash beginning of year	73	437
Cash end of year	$ 437	$ 93
Supplemental cash flows disclosures:		
Interest paid	$ -	$ -
Taxes paid	$ -	$ -
Supplemental non-cash financing disclosures:		
Issuance of convertible notes payable recorded as debt discount	$ -	$ 68
Conversion of convertible notes payable and accrued interest	$ 648	$ -
Fair value of warrant recorded as debt discount on issuance of convertible note payable	$ 390	$ -

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 Pharm, Ltd., on May 20, 2023. The Company is an early-stage biotechnology company, which is focused on the development of immunotherapy and cell therapy treatments for oncology.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, 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 incurred a net loss of $1,812 during the year ended December 31, 2023, and had a shareholders' deficit of $2,078 as of December 31, 2023. These factors raise substantial doubt, as defined under GAAP, about the Company's ability to continue as a going concern for the twelve months following the issuance of these consolidated financial statements. Management's plan 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 related to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

At December 31, 2023, the Company had cash on hand in the amount of $93. The ability to continue as a going concern is dependent on the Company attaining and maintaining profitable operations in the future and raising additional capital to meet its obligations and repay its liabilities arising from normal business operations when they come due. Since inception, the Company has funded its operations primarily through equity and debt financings and it expects to continue to rely on these sources of capital in the future.

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 the case of equity financing.

Stock Split

On April 28, 2022, the Company effected a 1.5-for-1 stock split of its common stock. The par value and the authorized shares of the Company's common stock were not adjusted as a result of the stock split. The accompanying consolidated financial statements and notes to the financial statements give retroactive effect to the stock split for all periods presented.

Reverse Stock Split

On May 10, 2023, the Company effected a 1-for-2.5 reverse stock split of its common stock. The par value and the authorized shares of the Company's common stock were not adjusted as a result of the reverse stock split. The accompanying consolidated financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

Reincorporation

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. The accompanying consolidated financial statements and notes to the financial statements give retroactive effect to the reincorporation for all periods presented.

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 wholly owned subsidiary, Enviro Therapeutics, Inc. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The Company regularly evaluates estimates and assumptions. The Company bases its estimates and assumptions on current facts, historical experience and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the accrual of costs and expenses that are not readily apparent from other sources. The actual results experienced by the Company may differ materially and adversely from the Company's estimates. To the extent there are material differences between the estimates and the actual results, future results of operations will be affected. Significant estimates in the accompanying consolidated financial statements include the valuation allowance on deferred tax assets and impairment analysis and useful life for intangible assets.

Cash

For the purpose of the statement of cash flows, cash includes currency on hand with banks and financial institutions.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash deposits. Accounts at each financial institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to certain limits. The Company does not maintain deposits in excess of federally insured limits.

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 Therapeutics, Inc. during the year ended December 31, 2021, with an acquisition cost of $800 (see Note 3). Amortization expense relating to the intangible asset during the years ended December 31, 2022 and 2023 was $160, respectively, with an unamortized balance of $542 and $382 at December 31, 2022 and 2023, 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 regardless of whether such carrying amount is zero or negative. 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, 2022 and 2023.

Net Loss Per Share

Net loss per share is calculated in accordance with ASC Topic 260, *Earnings Per Share*. Basic earnings per share ("EPS") is based on the weighted average number of common shares outstanding. Diluted EPS is based on the assumption that all dilutive securities are converted. When options or warrants are outstanding, dilution is computed by applying the treasury stock method. Under this method, options and warrants are assumed to be exercised at the beginning of the period (or at the time of issuance, if later), and funds obtained thereby are assumed to be used to purchase common stock at the average market price during the period. For the years ended December 31, 2022 and 2023, the basic and diluted shares outstanding were the same, as potentially dilutive shares were considered anti-dilutive. At December 31, 2022 and 2023, the potentially dilutive securities consisted of 180,000 and 150,000 shares relating to outstanding stock warrants, respectively.

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 Statement of Operations. As of December 31, 2022 and 2023, the Company had incurred $57 and $482 of deferred offering costs related to the Company's initial public offering of its common stock ("IPO").

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. The carrying amounts of the Company's convertible notes payable approximate their fair values as the interest rates of the notes are based on prevailing market rates.

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, 2022 and 2023.

The Company accounts for uncertainty in income taxes using a two-step approach to recognizing and measuring 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 $110 and $45 during the years ended December 31, 2022 and 2023.

Research and Development Costs

The Company expenses its research and development costs as incurred. Research and developments costs for the years ended December 31, 2022 and 2023 were $87 and $82, respectively.

Pro Forma Financial Information (unaudited)

Upon the closing of a qualified public offering (as defined in the Company's Certificate of Incorporation), all of the Company's convertible notes payable, including accrued interest, and certain accounts payable will automatically convert into shares of common stock. The accompanying unaudited pro forma balance sheet as of December 31, 2023 has been prepared to give effect to (i) the automatic conversion of all of the convertible notes payable and accrued interest into an aggregate of 334,375 shares of common stock as if the Company's proposed public offering had occurred on December 31, 2023, (ii) the issuance of 312,500 shares of common stock upon the conversion of certain accounts payable as of December 31, 2023 and (iii) the issuance of 1,664 shares of common stock upon the conversion of certain amounts due to related parties as of December 31, 2023, each in connection with the closing of this offering. The shares of common stock issuable and the proceeds expected to be received in the proposed public offering are excluded from such pro forma financial information.

The unaudited pro forma basic and diluted net loss per share in the accompanying statements of operations for the year ended December 31, 2023 have been computed to give effect to the automatic conversion of all convertible notes payable, amounts due to related parties, and certain accounts payable into shares of common stock. The unaudited pro forma basic and diluted net loss per share for the year ended December 31, 2023 was computed using the weighted average number of shares of common stock outstanding, including the pro forma effect of the conversion of all convertible notes payable and the related accrued interest, and certain accounts payable and amounts due to related parties, as if the Company's proposed public offering had occurred on January 1, 2023. The unaudited pro forma net loss per share does not include the shares expected to be sold or related proceeds to be received in the proposed public offering.

The following table summarizes the Company's unaudited pro forma net loss per share (in thousands except for share amounts and per share data):

	Year Ended December 31, 2023
Numerator:	
Net loss	$ (1,812)
Denominator:	
Weighted average number of common shares outstanding	10,382,515
Pro forma weighted average shares outstanding after giving effect to the conversion of convertible notes payable and certain accounts payable	648,539
Pro forma weighted average common shares outstanding	11,031,054
Pro forma net loss per share, basic and diluted	$ (0.16)

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, *Simplifying the Accounting for Income Taxes* which amends ASC 740 *Income Taxes* (ASC 740). This update is intended to simplify accounting for income taxes by removing certain exceptions to the general principles in ASC 740 and amending existing guidance to improve consistent application of ASC 740. This update is effective for fiscal years beginning after December 15, 2021. The guidance in this update has various elements, some of which are applied on a prospective basis and others on a retrospective basis with earlier application permitted. The Company is currently evaluating the effect of this ASU on the Company's financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06 ("ASU 2020-06") "*Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*." ASU 2020-06 reduces the number of accounting models for convertible debt instruments by eliminating the cash conversion and beneficial conversion accounting models. As a result, the Company's convertible debt instruments will be accounted for as a single liability measured at its amortized cost as long as no other features require bifurcation and recognition as derivatives. For contracts in an entity's own equity, the type of contracts primarily affected by this update are freestanding and embedded features that are accounted for as derivatives under the current guidance due to a failure to meet the settlement conditions of the derivative scope exception. The Company adopted ASU No. 2020-06 effective January 1, 2021 using the modified retrospective approach.

The Company accounted for convertible notes payable (when it has determined that the embedded conversion options should not be bifurcated from their host instruments) in accordance with ASC 470-20, *Debt with Conversion and Other Options* up through December 31, 2020. Accordingly, the Company recorded, when necessary, discounts to convertible notes payable for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements were amortized over the term of the related debt to their earliest date of redemption. The Company determined that the embedded conversion options in its issued convertible notes payable do not meet the definition of a derivative liability.

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. ASU 2021-04 provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. An issuer measures the effect of a modification or exchange as the difference between the fair value of the modified or exchanged warrant and the fair value of that warrant immediately before modification or exchange. ASU 2021-04 introduces a recognition model that comprises four categories of transactions and the corresponding accounting treatment for each category (equity issuance, debt origination, debt modification, and modifications unrelated to equity issuance and debt origination or modification). ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the guidance provided in ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date. Early adoption is permitted for all entities, including adoption in an interim period. If an entity elects to early adopt ASU 2021-04 in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The adoption of ASU 2021-04 is not expected to have a material impact on the Company's financial statements or 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 – ACQUISITION OF ENVIRO THERAPEUTICS, INC.

On June 3, 2021, the Company and Enviro Therapeutics, Inc. ("Enviro") entered into a share exchange agreement, whereby the Company acquired all of the common stock of Enviro in exchange for shares of the Company's common stock (the "Enviro-Kairos Share Exchange"). Pursuant to the Enviro-Kairos Share Exchange, the Enviro shareholders exchanged 100% of the issued and outstanding shares of Enviro (on a fully diluted basis) for 2,400,000 restricted shares of the Company's common stock.

The Company's Chairman, Chief Executive Officer and majority shareholder, was also a shareholder of Enviro who exercised control over Enviro. The acquisition of Enviro by the Company is being treated as a transaction between entities under common control resulting in the historical cost basis of Enviro's assets and liabilities being recognized, rather than the asset and liabilities being recorded at fair value as would be the case in a business combination between entities not under common control. The historical cost basis of Enviro's asset and liabilities is as follows:

Cash	$ 6
Intangible assets	800
Accounts payable	(51)
Advances from related parties	(129)
	$ 627

NOTE 4 – ADVANCES FROM 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, 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, $14 was owed on the advances. During the year ended December 31, 2022, the Company repaid $10 of the advances, and as of December 31, 2022 and 2023, a total of $4 was outstanding.

NOTE 5 – NOTE PAYABLE

In July 2020, the Company entered into a note payable agreement with another company under which the Company borrowed $50. The note accrues interest at 1% per annum, is unsecured and is due in July 2021. As of December 31, 2020, $50 was outstanding on the note. During the year ended December 31, 2021, the Company repaid $20 on the note, and as of December 31, 2021, $30 was outstanding on the note. During the year ended December 31, 2022, the Company repaid $30 on the note, and as of December 31, 2022, no amount was outstanding on the note.

NOTE 6 – CONVERTIBLE NOTES PAYABLE

Convertible notes payable consisted of the following as of December 31, 2022 and 2023:

	December 31, 2022	December 31, 2023
Convertible note payable (a)	$ -	$ -
Convertible note payable (b)	-	-
Convertible notes payable (c)	675	743
	675	743
Less: current portion	-	-
Convertible notes payable – long - term portion	$ 675	$ 743

(a) In August 2021, the Company entered into a convertible note payable agreement with an individual in the amount of $350. The note accrued interest at 10% per annum, was unsecured and was due the latter of August 2021 or the closing of a proposed merger by the Company. The note was convertible at the option of the noteholder to convert into shares of the Company's common stock at $4.17 per share. At December 31, 2021, principal of $350 and accrued and unpaid interest of $14, was owed on the note. During the year ended December 31, 2022, the note accrued interest of $23. In 2022, all the principal plus accrued and unpaid interest converted into 92,000 shares of the Company's common stock based on the principal and accrued interest due on the date of conversion. As of December 31, 2022 and 2023, no principal or accrued interest was outstanding on the note.

(b) During the year ended December 31, 2022, the Company entered into a convertible note payable agreement with the same individual in the amount of $250. The note accrued interest at 10% per annum, was unsecured and was due upon the closing of a proposed IPO transaction by the Company, or by July 2022, if the IPO transaction has not occurred by that date. The note included an original issue discount (OID) of 8.0%. The note was convertible at the option of the noteholder to convert into shares of the Company's common stock at $4.17 per share or will be automatically converted into shares of the Company's common stock at $4.17 per share upon the closing of an IPO transaction. The net proceeds received relating to the agreement were $230.

In connection with the convertible note payable, the Company issued the noteholder a warrant to purchase 150,000 shares of the Company's common stock for $4.17 per share. The warrant expires in March 2025. The Company calculated the relative fair value of the warrant issued to the noteholder to be $390 using a Black Scholes option pricing model and recognized a debt discount at the date of issuance in the same amount. The note discount is being amortized over the term of the note and the unamortized portion is recognized as a reduction to the carrying amount of the note. As the note matured during the year ended December 31, 2022, the Company amortized the entire amount of the debt discount, leaving no unamortized balance at December 31, 2022. As of December 31, 2022 and 2023, no principal or accrued interest was outstanding on the note.

In 2022, all of the principal plus accrued and unpaid interest from both convertible notes payable above totaling $600 of principal, plus accrued and unpaid interest of $48, converted into 154,782 shares of the Company's common stock based on the principal and accrued interest due on the date of conversion. As of December 31, 2022 and 2023, no principal or accrued interest was outstanding on the two notes.

(c) During the year ended December 31, 2022, the Company entered into several convertible note payable agreements with individuals and an entity in the aggregate total of $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 will have the choice of paying off the principal plus all accrued and unpaid interest, or the note's principal balance will increase to 110% of its original balance. The notes are convertible at the option of the noteholders to convert 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 relating to the agreements, net of expenses, were $564. As of December 31, 2022, $675 of principal was outstanding on the notes, and $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.

The Company accounted for the $68 increase in the principal balance as a debt discount. During the year ended December 31, 2023, the Company amortized $16 of debt discount, leaving an unamortized balance of $52 at December 31, 2023.

Also in connection with the convertible note agreements, the Company incurred debt issuance costs of $111, which the Company recorded as a debt discount during the year ended December 31, 2022. During the year ended December 31, 2022, the Company amortized $18 of debt discount, leaving an unamortized balance of $93 at December 31, 2022. During the year ended December 31, 2023, the Company amortized $40 of debt discount, leaving an unamortized balance of $53 at December 31, 2023. As of December 31, 2023, there was a total unamortized balance of $105.

In the event the Company closes its IPO, then the principal amount of $743, plus the accrued and unpaid interest of $60, will automatically convert into 334,375 shares of the Company's common stock based on the principal and accrued interest due as of December 31, 2023.

NOTE 7 – 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, 2022 and 2023, there were 10,334,357 and 10,562,640 shares of common stock issued and outstanding, respectively, and no shares of preferred stock outstanding, respectively.

Common Stock to be Issued for Services

In September 2020, the Company entered into a verbal agreement with a consulting firm to provide certain business development services to the Company. The agreement was formally executed in April 2021 but contained the same terms as the verbal agreement. The term of the agreement was from September 1, 2020 to January 31, 2021, which is the defined service period for the services to be performed and provided for the issuance of 2,100,000 restricted shares of the Company's common stock to the consulting firm. The shares vested over the term of the agreement and had a fair value on the date of the verbal agreement of $1,000. The shares were not issued to the consulting firm until 2022 and thus are categorized as Common Stock to be Issued on the accompanying December 31, 2021 consolidated Statement of Shareholders' Deficit.

Common Shares Issued in Connection with a Shareholder Dispute

During the year ended December 31, 2023, the Company issued 228,284 shares of its common stock to two shareholders relating to the settlement of a dispute. The Company valued the shares on the date of grant to be $913. The value of the shares was recorded in general and administrative expenses during the year ended December 31, 2023. Upon the issuance of the shares, the shareholders entered into agreements with the Company under which they agreed to the final settlement of the dispute.

Stock Warrants

The table below summarizes the Company's warrant activities for years ended December 31, 2022 and 2023:

	Number of Warrant Shares	Exercise Price Range Per Share	Weighted Average Exercise Price
Balance, December 31, 2021	120,000	$ 4.17 - 8.33	$ 5.23
Granted	150,000	4.17	4.17
Cancelled	–	–	–
Exercised	–	–	–
Forfeited/Expired	(90,000)	4.17	4.17
Balance, December 31, 2022	180,000	4.17 - 8.33	4.86
Granted	–	–	–
Cancelled	–	–	–
Exercised	–	–	–
Forfeited/Expired	(30,000)	8.33	8.33
Balance, December 31, 2023	150,000	$ 4.17	$ 4.17
Vested and exercisable, December 31, 2023	150,000	$ 4.17	$ 4.17

The following table summarizes information concerning outstanding and exercisable warrants as of December 31, 2023:

	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
$ 4.17	150,000	1.17	$ 4.17	150,000	1.17	$ 4.17

During the year ended December 31, 2022, the Company entered into a convertible note payable agreement with an individual in the amount of $250. In connection with that agreement, the Company granted a warrant to the lender to purchase up to 150,000 shares of the Company's common stock with an exercise price of $4.17 per share. The warrant expires in March 2025.

During the year ended December 31, 2021, the Company entered into a convertible note payable agreement with an individual in the amount of $350 (see Note 6). In connection with that agreement, the Company granted a warrant to the lender to purchase up to 90,000 shares of the Company's common stock with an exercise price of $4.17 per share. The warrant expired in August 2022. Also in 2021, the Company sold 60,000 shares of its common stock for net proceeds of $250. In connection with the sale, the Company issued a stock warrant to the shareholder to purchase 30,000 shares of the Company's common stock with an exercise price of $8.33 per share. The warrant expired in April 2023.

Also in 2022, the Company granted the underwriters for their IPO, two stock warrants in connection with bridge loans they assisted the Company in obtaining (see Note 6). The underwriters will be entitled to receive the number of warrant shares equal to 7% of the conversion shares that will be issued to the lenders at the time of the IPO. The warrants will be good for five years from the date of the IPO. However, the underwriters may not sell the shares underlying the warrants for a period of six months following the IPO. The exercise price for the warrants will be equal to 60% of the per share price of the Company's common stock sold in the IPO.

There was no intrinsic value for warrant shares outstanding at December 31, 2023.

NOTE 8 – 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, 2022 and 2023 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, 2022 and 2023.

A reconciliation of the differences between the effective and statutory income tax rates for the years ended December 31, 2022 and 2023 is shown below:

	2022		2023	
	Amount	Percent	Amount	Percent
Federal statutory rates	$ (221)	21.0%	$ (381)	21.0%
State income taxes	(84)	8.0%	(145)	8.0%
Permanent differences	18	(0.2)%	-	-%
Valuation allowance against net deferred tax assets	287	(28.8)%	526	(29.0)%
Effective rate	$ -	-%	$ -	-%

At December 31, 2022 and 2023, the significant components of the deferred tax assets and liabilities are summarized below:

	2022	2023
Deferred income tax assets:		
Net operating loss carryforwards	$ 604	$ 857
Amortization of intangibles	37	37
Accrued expenses	463	687
Total deferred income tax assets	1,104	1,581
Less: valuation allowance	(1,104)	(1,581)
Total deferred income tax assets	$ -	$ -

The valuation allowance increased by $218 and $477 in 2022 and 2023, respectively, as a result of the Company generating additional net operating losses.

The Company has recorded as of December 31, 2022 and 2023 a valuation allowance of $1,104 and $1,581, respectively, as it believes that it is more likely than not that the deferred tax assets will not be realized in future years. Management has based its assessment on the Company's lack of profitable operating history.

The Company conducts an analysis of its tax positions and has concluded that it has no uncertain tax positions as of December 31, 2022 and 2023.

The Company has net operating loss ("NOL") carryforwards of approximately $2,000 and are subject to IRS code section 382 limitations. Approximately $9 of the net operating loss carry-forwards begin to expire in 2031 and approximately $2,000 may be carried forward indefinitely. 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.

The 2021, 2022 and 2023 tax years are still subject to audit.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act was enacted on March 27, 2020. Among the business provisions, the CARES Act provided for various payroll tax incentives, changes to net operating loss carryback and carryforward rules, business interest expense limitation increases, and bonus depreciation on qualified improvement property. Additionally, the Consolidated Appropriations Act of 2021 was signed on December 27, 2020 which provided additional COVID relief provisions for businesses. The Company has evaluated the impact of both the Acts and has determined that any impact is not material to its financial statements.

NOTE 9 – COMMITMENTS

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

The Company has entered into four Exclusive License Agreements with Cedars 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 $500,000 (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 exclusive license agreement in item 4, the Company is required to pay an initial license fee of $50 upon the raising of $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.

Enviro Therapeutics

On June 2, 2021, the Company's wholly owned subsidiary, Enviro Therapeutics, Inc. (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, Enviro is required to pay an upfront license fee in the mid four-figures and low-five figures, respectively. Enviro is 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 shall also 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 derives 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 is 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 Enviro-Cedars License Agreements, the required milestone payments would total in the mid-to-high seven-figures.

Pursuant to the Enviro-Cedars License Agreements, Enviro is obligated to meet the following Commercialization Milestones. Pursuant to the Enviro-Cedars License Agreement (Endoglin Antagonism), Enviro is 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 is 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 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 Enviro-Cedars 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.

License Agreement with Tracon Pharmaceutical, Inc.

On May 21, 2021, Enviro entered into a License Agreement with Tracon Pharmaceutical, Inc. ("Tracon"). Pursuant to the Tracon License Agreement, Tracon granted 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" (all as defined or described in the Tracon License Agreement).

Pursuant to the Tracon License Agreement, Enviro paid Tracon an upfront fee of $100, and will pay Tracon an additional $500 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, and an additional $500 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 (the payment of the $100 and the two payments of $500 are referred to in the aggregate as the "Cash Consideration"). In addition, Enviro will pay Tracon a royalty of 3% of net sales on a country-by-country basis of the products subject to the Tracon License Agreement, and non-royalty payments of 3% of sublicensing fees.

Enviro issued Tracon equity ownership in Enviro equal to a number of shares of restricted common stock of Enviro equal to seven percent (7%) on a fully-diluted and converted basis of all common and preferred shares of Enviro (the "Tracon-Enviro Equity"). In connection with the Enviro-Kairos Share Exchange, the parties agreed that Tracon would receive, in exchange for its Enviro common stock, 420,000 restricted shares of Kairos Common Stock (which is equal to 1.41229% of the issued and outstanding shares of Kairos on a fully-diluted and converted basis) as the Tracon-Enviro Equity. Until such time as Tracon has received all of the Cash Consideration (as defined in the Tracon License Agreement), Enviro or its successor in interest, will issue to Tracon, without further consideration, any additional shares of 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). Notwithstanding the foregoing, if Tracon receives the full Cash Consideration within six (6) months of the effective date of the Tracon License Agreement, then Tracon will automatically return to Enviro (or any successor entity, if applicable) a number of restricted shares of the common stock of Enviro (or its successor) such that upon such return of shares Tracon will possess an amount of shares in Enviro (or its successor) equal to two percent (2%) on a fully-diluted and converted basis relative to the other Enviro shareholders who exchanged their shares in the Enviro-Kairos Share Exchange. The returned portion of the Tracon-Enviro Equity will automatically be terminated, cancelled and of no further force and effect.

Agreement with former Chief Financial Officer

The Company has an agreement with its former Chief Financial Officer that requires the Company to pay $50 upon the completion of raising more than $850 in debt or equity financing. No amount was owed at December 31, 2022 and 2023.

NOTE 10 – SUBSEQUENT EVENTS

Subsequent to December 31, 2023, the Company entered into agreements with Cedars-Sinai Medical Center (Cedars) under which Cedars agreed to convert $750 of the total accounts payable due to them of $942 into 312,500 shares of the Company's common stock upon the closing of the Company's IPO. The conversion price of the shares will be equal to 60% of the IPO closing price.

Subsequent to December 31, 2023, two officers and shareholders agreed to convert the $4 due to them into 1,664 shares of the Company's common stock, effective upon the closing of the Company's IPO. The conversion price of the shares will be equal to 60% of the IPO closing price.

Subsequent to December 31, 2023, the Company borrowed $72 from three of its officers. The loans accrue interest at 7.5%, are due in April 2025 and are unsecured.

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

	December 31, 2023	June 30, 2024 (Unaudited)	Pro Forma June 30, 2024 (Unaudited)
ASSETS			
Current Assets			
Cash	$ 93	$ 21	$ 21
Prepaid expenses	8	17	17
Total Current Assets	101	38	38
Deferred offering costs	482	690	690
Intangible assets, net	382	302	302
Total Other Assets	864	992	992
TOTAL ASSETS	$ 965	$ 1,030	$ 1,030
LIABILITIES AND SHAREHOLDERS' DEFICIT			
Current Liabilities			
Accounts payable and accrued expenses	$ 2,401	$ 2,901	$ 1,915
Due to related parties	4	4	-
Notes payable - officers	-	102	-
Total Current Liabilities	2,405	3,007	1,915
Convertible notes payable, net of debt discount of $105 and $66 at December 31, 2023 and June 30, 2024, respectively	638	677	-
Total Liabilities	3,043	3,684	1,915
Shareholders' Deficit			
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; 10,334,357 and 10,562,640 shares issued and outstanding, respectively; 11,291,937 shares issued and outstanding pro forma (unaudited)	11	11	11
Additional paid-in capital	4,123	4,123	5,958
Accumulated deficit	(6,212)	(6,788)	(6,854)
Total Shareholders' Deficit	(2,078)	(2,654)	(885)
TOTAL LIABILITIES AND SHAREHOLDERS' DEFICIT	$ 965	$ 1,030	$ 1,030

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2024	2023	2024
	(Unaudited)		(Unaudited)	
Revenues	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	36	63	42	228
General and administrative	176	159	296	286
Total operating expenses	212	222	338	514
Loss from operations	(212)	(222)	(338)	(514)
Other expenses:				
Interest expense	(14)	(12)	(24)	(23)
Debt discount amortization	(10)	(19)	(20)	(39)
Total other expenses	(24)	(31)	(44)	(62)
NET LOSS	$ (236)	$ (253)	$ (382)	$ (576)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.02)	$ (0.02)	$ (0.04)	$ (0.05)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING BASIC AND DILUTED	10,334,357	10,562,640	10,334,357	10,562,640
PRO FORMA BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.02)	$ (0.02)	$ (0.03)	$ (0.05)
PRO FORMA WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING BASIC AND DILUTED	10,962,699	11,215,807	10,962,699	11,215,807

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, March 31, 2023 (unaudited)	10,334,357	$ 10	$ 3,211	$ (4,546)	$ (1,325)
Net loss	-	-	-	(236)	(236)
Balance, June 30, 2023 (unaudited)	10,334,357	$ 10	$ 3,211	$ (4,782)	$ (1,561)
Balance, December 31, 2022	10,334,357	$ 10	$ 3,211	$ (4,400)	$ (1,179)
Net loss	-	-	-	(382)	(382)
Balance, June 30, 2023 (unaudited)	10,334,357	$ 10	$ 3,211	$ (4,782)	$ (1,561)
Balance, March 31, 2024 (unaudited)	10,562,640	$ 11	$ 4,123	$ (6,535)	$ (2,401)
Net loss	-	-	-	(253)	(253)
Balance, June 30, 2024 (unaudited)	10,562,640	$ 11	$ 4,123	$ (6,788)	$ (2,654)
Balance, December 31, 2023	10,562,640	$ 11	$ 4,123	$ (6,212)	$ (2,078)
Net loss	-	-	-	(576)	(576)
Balance, June 30, 2024 (unaudited)	10,562,640	$ 11	$ 4,123	$ (6,788)	$ (2,654)

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

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

	Six Months Ended June 30,	
	2023	**2024**
	(Unaudited)	
Cash Flows from Operating Activities		
Net loss	$ (382)	$ (576)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Amortization expense	80	80
Amortization of debt discount	20	39
Fair value of common stock issued in connection with shareholder dispute		
Changes in operating assets and liabilities:		
(Increase) Decrease in:		
Prepaid expenses	(26)	(9)
(Decrease) Increase in:		
Accounts payable and accrued expenses	232	334
Net cash provided by (used in) operating activities	(76)	(132)
Cash Flows from Financing Activities		
Proceeds from notes payable - officers	-	102
Payment of deferred offering costs	(129)	(42)
Net cash used in financing activities	(129)	60
Net decrease in cash	(205)	(72)
Cash beginning of period	437	93
Cash end of period	$ 232	$ 21
Supplemental cash flows disclosures:		
Interest paid	$ -	$ -
Taxes paid	$ -	$ -
Supplemental non-cash financing disclosures:		
Accrual for deferred offering costs	$ 72	$ 166

The accompanying notes are an integral part of these condensed 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 Pharm, 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.

Basis of Presentation of Unaudited Financial Information

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all normal recurring adjustments considered necessary for a fair presentation have been included. Operating results for the six months ended June 30, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024.

Going Concern

The accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. As reflected in the accompanying condensed consolidated financial statements, the Company incurred a net loss of $576 during the six months ended June 30, 2024, and had a shareholders' deficit of $2,654 as of June 30, 2024. These factors raise substantial doubt, as defined under GAAP, about the Company's ability to continue as a going concern for the twelve months following the issuance of these consolidated financial statements. Management's plan 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 related to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

At June 30, 2024, the Company had cash on hand in the amount of $21. The ability to continue as a going concern is dependent on the Company attaining and maintaining profitable operations in the future and raising additional capital to meet its obligations and repay its liabilities arising from normal business operations when they come due. Since inception, the Company has funded its operations primarily through equity and debt financings and it expects to continue to rely on these sources of capital in the future.

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 the case of equity financing.

Reverse Stock Split

On May 10, 2023, the Company effected a 1-for-2.5 reverse stock split of its common stock. The par value and the authorized shares of the Company's common stock were not adjusted as a result of the reverse stock split. The accompanying condensed consolidated financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

Reincorporation

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. The accompanying condensed consolidated financial statements and notes to the financial statements give retroactive effect to the reincorporation for all periods presented.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Consolidation

The accompanying condensed 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 wholly owned subsidiary, Enviro Therapeutics, Inc. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The Company regularly evaluates estimates and assumptions. The Company bases its estimates and assumptions on current facts, historical experience and various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the accrual of costs and expenses that are not readily apparent from other sources. The actual results experienced by the Company may differ materially and adversely from the Company's estimates. To the extent there are material differences between the estimates and the actual results, future results of operations will be affected. Significant estimates in the accompanying condensed consolidated financial statements include the valuation allowance on deferred tax assets and impairment analysis and useful life for intangible assets.

Cash

For the purpose of the statement of cash flows, cash includes currency on hand with banks and financial institutions.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash deposits. Accounts at each financial institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to certain limits. The Company does not maintain deposits in excess of federally insured limits.

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 Therapeutics, Inc. during the year ended December 31, 2021, with an acquisition cost of $800. Amortization expense relating to the intangible asset during the six months ended June 30, 2023 and 2024 was $80, respectively, with an unamortized balance of $382 and $302 at December 31, 2023 and June 30, 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 regardless of whether such carrying amount is zero or negative. 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 six months ended June 30, 2023 and 2024.

Net Loss Per Share

Net loss per share is calculated in accordance with ASC Topic 260, *Earnings Per Share*. Basic earnings per share ("EPS") is based on the weighted average number of common shares outstanding. Diluted EPS is based on the assumption that all dilutive securities are converted. When options or warrants are outstanding, dilution is computed by applying the treasury stock method. Under this method, options and warrants are assumed to be exercised at the beginning of the period (or at the time of issuance, if later), and funds obtained thereby are assumed to be used to purchase common stock at the average market price during the period. For the six months ended June 30, 2023 and 2024, the basic and diluted shares outstanding were the same, as potentially dilutive shares were considered anti-dilutive. At June 30, 2023 and 2024, the potentially dilutive securities consisted of 150,000 shares relating to outstanding stock warrants, respectively.

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 Statement of Operations. As of December 31, 2023 and June 30, 2024, the Company had incurred $482 and $690 of deferred offering costs, respectively, related to the Company's initial public offering of its common stock ("IPO").

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. The carrying amounts of the Company's convertible notes payable and notes payable - officers approximate their fair values as the interest rates of the notes are based on prevailing market rates.

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, 2023 and June 30, 2024.

The Company accounts for uncertainty in income taxes using a two-step approach to recognizing and measuring 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 condensed consolidated Statements of Operations. Patent expenses were $21 and $9 during the six months ended June 30, 2023 and 2024.

Research and Development Costs

The Company expenses its research and development costs as incurred. Research and developments costs for the six months ended June 30, 2023 and 2024 were $42 and $228, respectively.

Pro Forma Financial Information (unaudited)

Upon the closing of a qualified public offering (as defined in the Company's Certificate of Incorporation), all of the Company's convertible notes payable and notes payable from officers, including accrued interest, and certain accounts payable will automatically convert into shares of common stock. The accompanying unaudited pro forma balance sheet as of June 30, 2024 has been prepared to give effect to (i) the automatic conversion of all of the convertible notes payable and notes payable - officers and the related accrued interest into an aggregate of 369,248 shares of common stock as if the Company's proposed public offering had occurred on June 30, 2024, (ii) the issuance of 312,500 shares of common stock upon the conversion of certain accounts payable as of June 30, 2024, (iii) the issuance of 45,885 shares of common stock upon the conversion of accounts payable due to one of its officers as of June 30, 2024 and (iv) the issuance of 1,664 shares of common stock upon the conversion of certain amounts due to related parties as of June 30, 2024, each in connection with the closing of this offering. The shares of common stock issuable and the proceeds expected to be received in the proposed public offering are excluded from such pro forma financial information.

The unaudited pro forma basic and diluted net loss per share in the accompanying statements of operations for the six months ended June 30, 2024 have been computed to give effect to the automatic conversion of all convertible notes payable, amounts due to related parties, and certain accounts payable into shares of common stock. The unaudited pro forma basic and diluted net loss per share for the six months ended June 30, 2024 was computed using the weighted average number of shares of common stock outstanding, including the pro forma effect of the conversion of all convertible notes payable and the related accrued interest, and certain accounts payable and amounts due to related parties, as if the Company's proposed public offering had occurred on January 1, 2024. The unaudited pro forma net loss per share does not include the shares expected to be sold or related proceeds to be received in the proposed public offering.

The following table summarizes the Company's unaudited pro forma net loss per share (in thousands except for share amounts and per share data):

	Six months ended June 30, 2024
Numerator:	
Net loss	$ (576)
Denominator:	
Weighted average number of common shares outstanding	10,562,640
Pro forma weighted average shares outstanding after giving effect to the conversion of convertible notes payable, notes payable from officers and certain accounts payable	729,297
Pro forma weighted average common shares outstanding	11,291,937
Pro forma net loss per share, basic and diluted	$ (0.05)

Recent Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosure, which is intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expense categories that are regularly provided to the chief operating decision maker and included in each reported measure of a segment's profit or loss. The update also requires all annual disclosures about a reportable segment's profit or loss and assets to be provided in interim periods and for entities with a single reportable segment to provide all the disclosures required by ASC 280, Segment Reporting, including the significant segment expense disclosures. The Company adopted ASU 2023-07 beginning January 1, 2024. The Company does not believe the impact of the new guidance and related codification improvements had a material impact to its financial position, results of operations and cash flows.

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 – ADVANCES FROM 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, all of which remained outstanding at December 31, 2021. The advances accrue no interest, are unsecured and are due on demand. As of December 31, 2021, $14 was owed on the advances. During the year ended December 31, 2022, the Company repaid $10 of the advances, and as of December 31, 2023 and June 30, 2024, a total of $4 was outstanding.

NOTE 4 –NOTES PAYABLE - OFFICERS

During the six months ended June 30, 2024, the Company entered into note payable agreements with three of its officers in the aggregate total of $102. The notes accrue interest at 7.5% per annum, are unsecured and are due one year from the date of issuance. During the six months ended June 30, 2024, the notes accrued interest of $1 and as of June 30, 2024, $102 of principal was outstanding on the notes and $1 of accrued and unpaid interest.

In connection with the agreements, the officers agreed to automatically convert the principal and accrued and unpaid interest into shares of the Company's common stock at the IPO price per share upon the closing of an IPO transaction. In the event the Company closes its IPO, then the principal amount of $102, plus the accrued and unpaid interest of $1, will automatically convert into 25,792 shares of the Company's common stock based on the principal and accrued interest due as of June 30, 2024.

NOTE 5 – CONVERTIBLE NOTES PAYABLE

During the year ended December 31, 2022, the Company entered into several convertible note payable agreements with individuals and an entity in the aggregate total of $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 will have the choice of paying off the principal plus all accrued and unpaid interest, or the note's principal balance will 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 relating to the agreements, net of expenses, were $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.

The Company accounted for the $68 increase in the principal balance as a debt discount. During the year ended December 31, 2023, the Company amortized $16 of debt discount, leaving an unamortized balance of $52 at December 31, 2023.

Also, in connection with the convertible note agreements, the Company incurred debt issuance costs of $111, which the Company recorded as a debt discount during the year ended December 31, 2022. During the year ended December 31, 2022, the Company amortized $18 of debt discount, leaving an unamortized balance of $93 at December 31, 2022. During the year ended December 31, 2023, the Company amortized $40 of debt discount, leaving an unamortized balance of $53 at December 31, 2023.

As of December 31, 2023, there was a total unamortized balance of $105. During the six months ended June 30, 2024, the Company amortized $39 of debt discount, leaving an unamortized balance of $66 at June 30, 2024. As of June 30, 2024, $743 of principal was outstanding on the notes and $82 of accrued and unpaid interest.

In the event the Company closes its IPO, then the principal amount of $743, plus the accrued and unpaid interest of $82, will automatically convert into 343,456 shares of the Company's common stock based on the principal and accrued interest due as of June 30, 2024.

NOTE 6 – 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, 2023 and June 30, 2024, there were 10,562,640 shares of common stock issued and outstanding, respectively, and no shares of preferred stock outstanding, respectively.

Stock Warrants

The table below summarizes the Company's warrant activities for six months ended June 30, 2024:

	Number of Warrant Shares	Exercise Price Range Per Share	Weighted Average Exercise Price
Balance, December 31, 2023	150,000	$ 4.17	$ 4.17
Granted	–	–	–
Cancelled	–	–	–
Exercised	–	–	–
Forfeited/Expired	–	–	–
Balance, June 30, 2024	150,000	$ 4.17	$ 4.17
Vested and exercisable, June 30, 2024	150,000	$ 4.17	$ 4.17

The following table summarizes information concerning outstanding and exercisable warrants as of June 30, 2024:

	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
$ 4.17	150,000	0.75	$ 4.17	150,000	0.75	$ 4.17
$ 4.17	150,000	0.75	$ 4.17	150,000	0.75	$ 4.17

There was no intrinsic value for warrant shares outstanding at June 30, 2024.

NOTE 7 – COMMITMENTS

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

The Company has entered into four Exclusive License Agreements with Cedars 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 $500,000 (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 listed 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.

Enviro Therapeutics

On June 2, 2021, the Company’s wholly owned subsidiary, Enviro Therapeutics, Inc. (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, Enviro is required to pay an upfront license fee in the mid four-figures and low-five figures, respectively. Enviro is 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 shall also 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 derives 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 is 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 Enviro-Cedars License Agreements, the required milestone payments would total in the mid-to-high seven-figures.

Pursuant to the Enviro-Cedars License Agreements, Enviro is obligated to meet the following Commercialization Milestones. Pursuant to the Enviro-Cedars License Agreement (Endoglin Antagonism), Enviro is 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 is 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 Enviro-Cedars 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.

License Agreement with Tracon Pharmaceutical, Inc.

On May 21, 2021, Enviro entered into a License Agreement with Tracon Pharmaceutical, Inc. ("Tracon"). Pursuant to the Tracon License Agreement, Tracon granted 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" (all as defined or described in the Tracon License Agreement).

Pursuant to the Tracon License Agreement, Enviro paid Tracon an upfront fee of $100, and will pay Tracon an additional $500 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, and an additional $500 within 10 days of its or its successor's completion of one or more financings through the sale of equity (or debt convertible into equity) in an amount of $22,000 (the payment of the $100 and the two payments of $500 are referred to in the aggregate as the "Cash Consideration"). In addition, Enviro will pay Tracon a royalty of 3% of net sales on a country-by-country basis of the products subject to the Tracon License Agreement, and non-royalty payments of 3% of sublicensing fees.

Enviro issued Tracon equity ownership in Enviro equal to a number of shares of restricted common stock of Enviro equal to seven percent (7%) on a fully-diluted and converted basis of all common and preferred shares of Enviro (the "Tracon-Enviro Equity"). In connection with the Enviro-Kairos Share Exchange, the parties agreed that Tracon would receive, in exchange for its Enviro common stock, 420,000 restricted shares of Kairos Common Stock (which is equal to 1.41229% of the issued and outstanding shares of Kairos on a fully-diluted and converted basis) as the Tracon-Enviro Equity. Until such time as Tracon has received all of the Cash Consideration (as defined in the Tracon License Agreement), Enviro or its successor in interest, will issue to Tracon, without further consideration, any additional shares of 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). Notwithstanding the foregoing, if Tracon receives the full Cash Consideration within six (6) months of the effective date of the Tracon License Agreement, then Tracon will automatically return to Enviro (or any successor entity, if applicable) a number of restricted shares of the common stock of Enviro (or its successor) such that upon such return of shares Tracon will possess an amount of shares in Enviro (or its successor) equal to two percent (2%) on a fully-diluted and converted basis relative to the other Enviro shareholders who exchanged their shares in the Enviro-Kairos Share Exchange. The returned portion of the Tracon-Enviro Equity will automatically be terminated, cancelled and of no further force and effect.

Agreement with former Chief Financial Officer

The Company has an agreement with its former Chief Financial Officer that requires the Company to pay $50 upon the completion of raising more than $850 in debt or equity financing. No amount was owed at December 31, 2023 and June 30, 2024.

NOTE 8 – SUBSEQUENT EVENTS

Subsequent to June 30, 2024, the Company borrowed $40 from one of its officers. The loans accrue interest at 7.5%, are due in July and August 2025 and are unsecured.

In addition, three officers entered into amendments to previously issued loan agreements pursuant to which they agreed to convert a total of $102 of promissory notes into 25,792 shares of the Company's common stock, at a $4.00 per share conversion price (see Note 4).

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.

1,550,000 Shares

Common Stock

PROSPECTUS

Boustead Securities, LLC **EF Hutton LLC**

Sutter Securities, Inc.

Through and including October 11, 2024 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.