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

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2025

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

For the transition period from _____ to _____

Commission file number 001-40582

UNICYCIVE THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**81-3638692**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1975 W. El Camino Real, Suite 204 Mountain View, CA	**94040**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(650) 351-4495**

4300 El Camino Real, Suite 210
Los Altos, CA 94022
(Former name or former address, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	UNCY	The Nasdaq Stock Market, LLC

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

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

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting stock and non-voting common equity held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter ended June 30, 2025 was $64,310,247 based upon the closing price of the registrant's common stock of $4.77 on The Nasdaq Capital Market as of that date.

The number of shares of common stock outstanding as of March 30, 2026 was 25,237,782.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's proxy statement, which will be filed with the Securities and Exchange Commission pursuant to Schedule 14A in connection with the registrant's 2026 Annual Meeting of Stockholders (the "2026 Proxy Statement"), are incorporated by reference into Part III of this Annual Report on Form 10-K. Except with respect to information specifically incorporated by reference in this Annual Report, the 2026 Proxy Statement is not deemed to be filed as part hereof.

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CAUTIONARY NOTE ON FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by such forward-looking terminology as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. Our forward-looking statements are based on a series of expectations, assumptions, estimates and projections about our company, are not guarantees of future results or performance and involve substantial risks and uncertainty. We may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Our business and our forward-looking statements involve substantial known and unknown risks and uncertainties, including the risks and uncertainties inherent in our statements regarding:

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues, and capital requirements;
- our ability to continue as a going concern;
- our need to raise substantial additional capital to fund our operation;
- the success, cost, and timing of our clinical trials;
- our dependence on third parties in the conduct of our clinical trials;
- our ability to obtain the necessary regulatory approvals to market and commercialize our product candidates;
- the ultimate impact of the COVID-19 pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole;
- the potential that results of pre-clinical and clinical trials indicate our current product candidates or any future product candidates we may seek to develop are unsafe or ineffective;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current and future product candidates;
- our ability to protect our intellectual property rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our intellectual property rights;

- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated or otherwise violated their intellectual property rights and that we may incur substantial costs and be required to devote substantial time defending against claims against us;

- our reliance on third-party suppliers and manufacturers;

- the success of competing therapies and products that are or become available;

- our ability to expand our organization to accommodate potential growth and our ability to retain and attract key personnel;

- the potential for us to incur substantial costs resulting from product liability lawsuits against us and the potential for these product liability lawsuits to cause us to limit our commercialization of our product candidates;

- market acceptance of our product candidates, the size and growth of the potential markets for our current product candidates and any future product candidates we may seek to develop, and our ability to serve those markets; and

- the successful development of our commercialization capabilities, including sales and marketing capabilities.

All of our forward-looking statements are as of the date of this Annual Report on Form 10-K only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of, or any material adverse change in, one or more of the risk factors or risks and uncertainties referred to in this Annual Report on Form 10-K or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the U.S. Securities and Exchange Commission (the "SEC") could materially and adversely affect our business, prospects, financial condition, and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Annual Report on Form 10-K, even if such results, changes, or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Annual Report on Form 10-K that modify or impact any of the forward-looking statements contained in this Annual Report on Form 10-K will be deemed to modify or supersede such statements in this Annual Report on Form 10-K.

This Annual Report on Form 10-K may include market data and certain industry data and forecasts, which we may obtain from internal company surveys, market research, consultant surveys, publicly available information, reports of governmental agencies and industry publications, articles, and surveys. Industry surveys, publications, consultant surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. While we believe that such studies and publications are reliable, we have not independently verified market and industry data from third-party sources.

RISK FACTOR SUMMARY

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors," that represent challenges that we face in connection with the successful implementation of our strategy. The occurrence of one or more of the events or circumstances described in the section titled "Risk Factors," alone or in combination with other events or circumstances, may have an adverse effect on our business, cash flows, financial condition and results of operations. Such risks include, but are not limited to:

Risks Relating to Our Financial Position and Capital Needs

- We have generated no product revenue to date and our future profitability is uncertain.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our product candidates on unfavorable terms to us.
- You may experience dilution, subordination of stockholder rights, preferences, and privileges, and decrease in market price of our common stock as a result of our private placement in March 2023.

Risks Related to our Business

- The marketing approval process of the FDA is lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our current product candidates and future product candidates we intend to develop, our business will be substantially harmed.
- We may encounter substantial delays in completing our clinical studies which in turn will require additional costs, or we may fail to demonstrate adequate safety and efficacy to the satisfaction of applicable regulatory authorities.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our product candidates and our ability to generate revenue will be impaired.
- Even if our product candidates receive marketing approval, they 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 are able to commercialize our product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.
- Our reliance on third parties heightens the risks faced by our business.
- We have no experience manufacturing product candidates on a clinical or commercial scale and will be dependent on third parties for the manufacture of our product candidates. If we experience problems with any of these third parties, they could delay clinical development or marketing approval of our product candidates or our ability to sell any approved products.
- Our products will face significant competition, and if they are unable to compete successfully, our business will suffer.
- Security threats to our information technology infrastructure and/or our physical buildings could expose us to liability and damage our reputation and business.

Risks Relating to our Intellectual Property

- We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed alleged trade secrets.
- Our intellectual property may not be sufficient to protect our product candidates from competition, which may negatively affect our business as well as limit our partnership or acquisition appeal.

General Risk Factors

- Our common stock may be delisted from The Nasdaq Capital Market if we fail to comply with continued listing standards.
- Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.
- We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares, except we have agreed to pay cash dividends in the event oxylanthanum carbonate is approved by the FDA and commercial sales is commenced

PART I

Throughout this Annual Report on Form 10-K, references to "we," "our," "us," the "Company," "Unicycive," or "Unicycive Therapeutics" refer to Unicycive Therapeutics, Inc.

ITEM 1. BUSINESS

Overview

We are a clinical-stage biotechnology company focused on identifying, developing, and commercializing innovative therapies to address significant unmet medical needs, with an initial focus on kidney disease. Founded in 2016, Unicycive was established to create a streamlined and efficient drug development platform capable of accelerating the advancement of promising therapies from discovery to commercialization. Currently, our two programs are focused on kidney disease, an area we believe we have the potential to offer medical benefit. Our initial focus is on developing drugs and getting them approved in the U.S., and then to partner with global biopharmaceutical companies in the rest of the world. As we grow the company and build our team, we intend to focus on identifying medical conditions within and outside of kidney disease. Our business model is to license technologies and drugs in order to pursue development, regulatory approval, and commercialization of those products in global markets. Many biotechnology companies utilize similar strategies of in-licensing and then developing and commercializing drugs. We believe, however, that our management team's broad network, expertise in the biopharmaceutical industry, and successful track record gives us an advantage in identifying and bringing these assets into our company.

Our current development programs are focused on two novel therapies: oxylanthanum carbonate, a next-generation phosphate binder for the treatment of hyperphosphatemia in chronic kidney disease patients on dialysis, and UNI-494, a novel drug candidate in development for the treatment of acute kidney injury. oxylanthanum carbonate and UNI-494 were initially developed by and licensed to us from Spectrum Pharmaceuticals ("Spectrum") and Sphaera Pharma, respectively. Spectrum conducted a Phase 1 clinical trial with oxylanthanum carbonate in 2012, prior to the grant of our license in 2018. Sphaera conceived and performed initial characterization of various potential pro-drug linkers, including the initial patent application. As discussed herein, after completing IND enabling preclinical studies, we have completed a Phase I clinical study in healthy volunteers with UNI-494 in 2024.

Chronic kidney disease (CKD) is the gradual loss of kidney (renal) function that can get worse over time leading to lasting damage and possibly Stage 5 or end-stage renal disease (ESRD). CKD affects nearly 36 million Americans; approximately 550,000 of them have end stage renal disease and require dialysis. Hyperphosphatemia is common in people with CKD and has been directly linked to increased morbidity and mortality for people on dialysis. For an estimated 75% of people in the U.S. on dialysis, hyperphosphatemia remains uncontrolled due to challenges with the six currently available phosphate binders, namely insufficient potency, pill burden and unpalatable formulations. To address this significant and growing challenge, Unicycive is developing oxylanthanum carbonate, which leverages proprietary nanoparticle technology to address the shortcomings of current therapies by delivering higher potency that enables fewer and smaller pills — all in a formulation that is more acceptable for patients because it is swallowed, not chewed. With OLC, if approved, people on dialysis and their physicians may have a better option to control hyperphosphatemia.

AKI is a sudden episode of kidney failure or kidney damage (within the first 90 days of injury). After 90 days, the patient is considered to have progressed into CKD. AKI affects more than 2 million U.S. patients and costs the healthcare system in excess of $9 billion per year. More than 300,000 patients per year in the U.S. die due to AKI. Currently there are no FDA approved medicines to treat DGF and/or AKI. Treatment options for AKI include continuous renal replacement therapy, renal transplant, and dialysis. In most cases the damage to the kidney is irreversible, and the patient needs to have a renal transplant or be on dialysis for life. Therefore, there is a high unmet medical need. If approved, UNI-494 has the potential to be a first-in-class drug for the treatment of AKI.

We operate with a sense of urgency to bring new treatments to patients faster, leveraging our team's expertise, operational efficiency, and strategic focus on high-value opportunities within the renal space. Through this approach, we aim to deliver innovative therapies that provide meaningful clinical and economic benefits for patients, providers, and healthcare systems.

Pipeline

Our proprietary pipeline is comprised of our two product candidates – oxylanthanum carbonate and UNI-494 – which are described below in **Figure 1**:

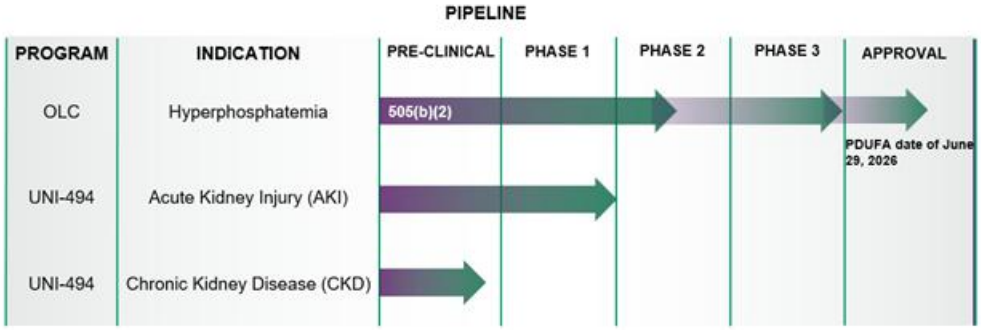


Figure 1: Unicycive Therapeutics' Pipeline

Oxylanthanum Carbonate

Oxylanthanum carbonate (lanthanum dioxycarbonate) is an investigational next-generation lanthanum-based phosphate binding agent being developed for the treatment of hyperphosphatemia in CKD patients on dialysis.

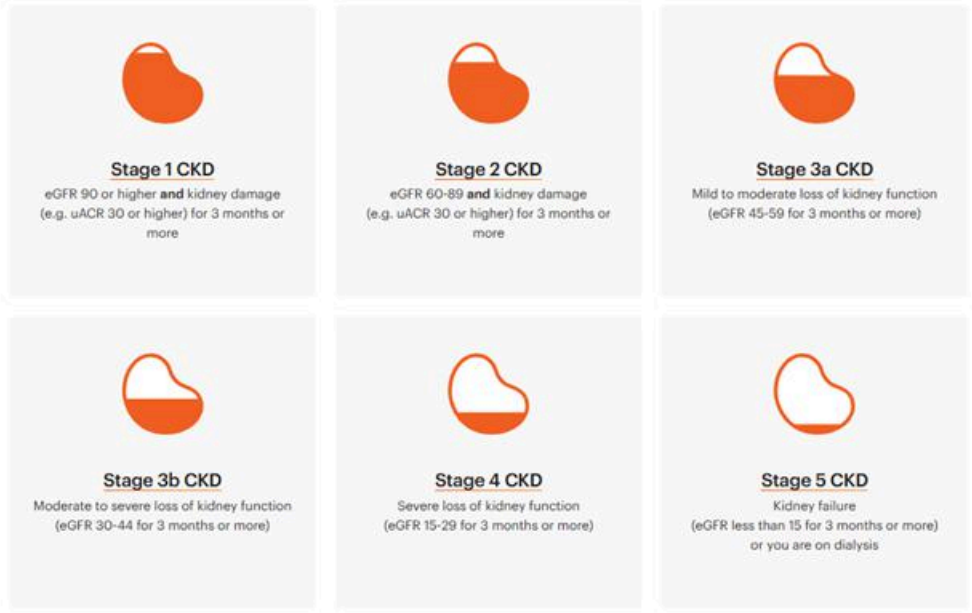
Oxylanthanum carbonate is a phosphate binder for the treatment of hyperphosphatemia in patients with CKD on dialysis and is intended to be administered as a tablet that will be swallowed whole at mealtimes. CKD patients typically have co-morbidities, which often require them to be on strict pill schedules. Current phosphate binder products involve patients needing to take a large number of pills daily, some of which are large and/or must be chewed, often resulting in poor adherence to the prescribed drug therapy.

By virtue of its novel nanoparticle technology, OLC leverages the high phosphate binding potency of lanthanum in a palatable dose form that has the potential to substantially reduce the pill burden volume for patients. In this regard, we believe that the combined effect of smaller pill size, lower number of pills, and improved palatability with Oxylanthanum carbonate will compete favorably with currently available phosphate binders and may lead to improved patient compliance/adherence and more effective disease management.

We are seeking the U.S. Food and Drug Administration (FDA) approval of OLC via the 505(b)(2) regulatory pathway. In September 2024, we submitted a New Drug Application (NDA) for OLC to the FDA. In November 2024 we announced the FDA had accepted its NDA and set a Prescription Drug User Fee Act (PDUFA) target action date of June 28, 2025. In June 2025, the FDA issued us a Complete Response Letter (CRL) notifying us that a third-party manufacturing vendor of its main contract development and manufacturing organization (CDMO) was cited for deficiencies following a cGMP inspection. No other concerns have been identified to us, including pre-clinical, clinical, or safety data submitted as part of the NDA. In October 2025, we held a Type A meeting with the FDA to discuss the resolution of the single deficiency identified in the CRL related to the compliance status of a third-party manufacturing vendor. Following receipt of the official meeting minutes from the Type A meeting and engaging in discussions with its third-party manufacturing vendor, we resubmitted its NDA to the FDA in December 2025. In January 2026, the FDA accepted the resubmission of the NDA for OLC, deeming the resubmission to be a Class II complete response which has a six-month review period from the date of resubmission, and set a PDUFA) target action date of June 29, 2026.

Disease Overview: Hyperphosphatemia

Chronic kidney disease (CKD) is the gradual loss of kidney (renal) function that can get worse over time leading to lasting damage and possibly Stage 5 or end-stage renal disease (ESRD). The stages of chronic kidney disease are shown below in **Figure 2**.



eGFR = estimated glomerular filtration rate (a measure of kidney function)

Image Source: https://www.kidney.org/kidney-topics/stages-chronic-kidney-disease-ckd

Figure 2: **Stages of Chronic Kidney Disease**

According to the United States Renal Data System (USRDS) 2022 Annual Data Report, 30 million (14%) of adults in the United States are estimated to have CKD and, of these, approximately 13 million patients have advanced CKD (stage 3-5). Complications of CKD include electrolyte imbalances, fluid build-up, anemia, bone disease, and heart disease. Most patients with Stage 5 CKD (ESRD) either undergo kidney transplantations or go on dialysis. The 2023 USRDS annual report indicates that there were 541,326 prevalent dialysis patients in 2021 (the latest reported year), and of those, approximately 450,000 patients (~80%) take phosphate binders to control hyperphosphatemia. The prevalent U.S. dialysis population has grown at an average yearly rate of 3.5% over the past decade. The number of patients with ESRD in the U.S. is increasing steadily and is projected to reach between 971,000 and 1,259,000 patients in 2030.

Hyperphosphatemia is a bone and mineral metabolism disorder in which elevated phosphorus levels in the blood lead to cardiovascular complications and vascular calcification (hardening). According to Kidney Disease Improving Global Outcomes (KDIGO) guidelines, hyperphosphatemia is defined as an abnormally high serum phosphorus concentration >4.5 mg/dL. In CKD, hyperphosphatemia is caused by a chronic dysregulation of serum phosphorus levels as a result of progressive kidney damage. In healthy people, normal serum phosphorus levels are maintained in the body by the absorption from food and subsequent excretion from the body via urine and feces. In people with CKD, not enough phosphate is excreted, leading to elevated levels of phosphorus in the blood.

According to a 2009 paper authored by Covic, hyperphosphatemia is associated with increased risk of cardiovascular disease, metabolic bone disease, and deaths from all-causes (all-cause mortality). According to a study completed by Palmer in 2011, it is estimated that all-cause mortality is increased by 18% for every 1 mg/dL increase in serum phosphorus concentration.

Current Treatment of Hyperphosphatemia

The treatment goal for patients with hyperphosphatemia is focused on controlling the level of phosphate in the body. KDIGO guidelines recommend three main strategies for managing hyperphosphatemia: dietary intake restrictions, use of phosphate binders, and dialysis, as shown in **Figure 3** below.

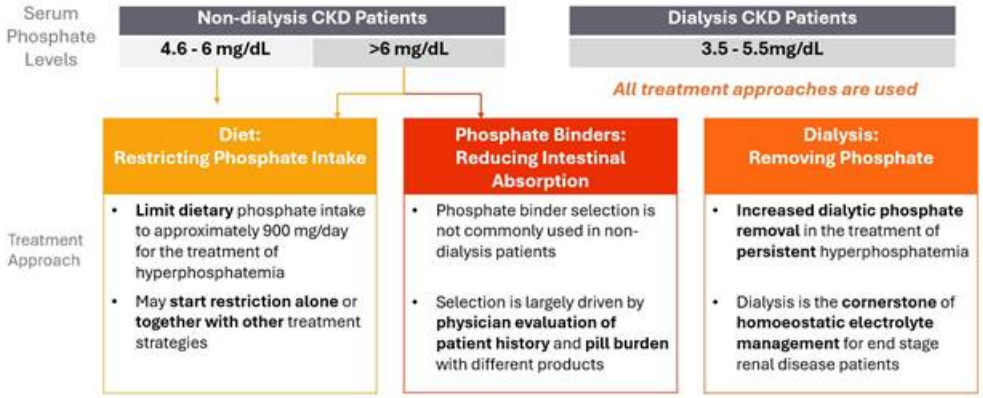


Figure 3: KDIGO Guidelines Recommend Three Main Strategies for Managing Hyperphosphatemia

While KDIGO guidelines do not recommend one phosphate binder over another, they do recommend restricting the dose of calcium-based binders and avoiding long-term use of aluminum-containing binders. This means that physicians prescribe their medication of choice, usually based on clinical factors and patient preferences. Utilization of calcium-based binders is discouraged by the most recent KDOQI/KDIGO guidelines due to mounting clinical evidence that excess calcium load from calcium-based phosphate binder is associated with hypercalcemia and cardiovascular calcification which has been associated with an increased risk of morbidity (disease) and mortality (death).

According to data from the Dialysis Outcomes and Practice Patterns Study (DOPPS) in 2021, 82% of U.S. dialysis patients were prescribed phosphate binders, which equates to approximately 450,000 patients.

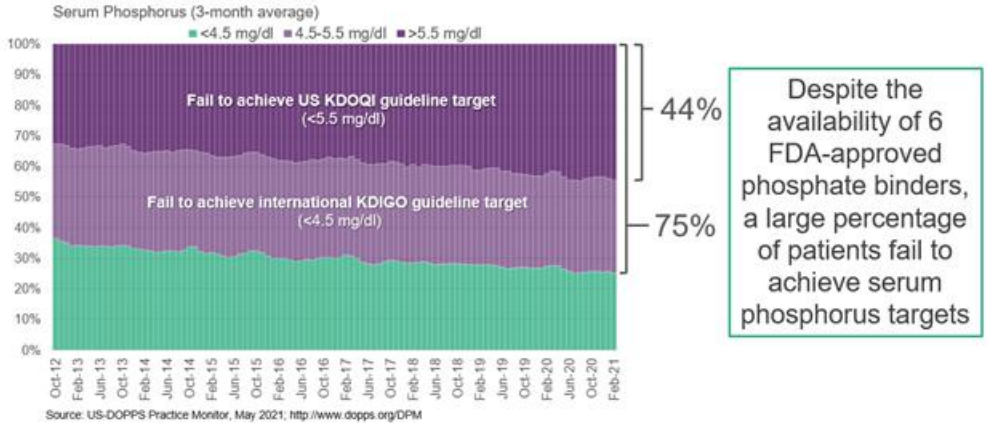
Unmet Medical Need in the Management of Hyperphosphatemia

The brief descriptions of the mechanism of action and what we believe to be the advantages and disadvantages of various phosphate binders are shown below in **Figure 4**.

Phosphate Binders	Mechanisms of Action	Form	Advantages	Disadvantages	Examples of Branded Products
Calcium carbonate/acetate	Forms insoluble phosphate complexes in the gut	Chewable and swallowed tablets	Moderately effective, relatively inexpensive	Hypercalcemia, high pill burden, reported to cause vascular calcification	PhosLo, Calphron, Tums, Caltrate
Sevelamer hydrochloride/carbonate	An anion exchange resin	Swallowed tablets and powder	Calcium-free, lipid-lowering effect	Low phosphate binding capacity, high pill burden, GI adverse effects	Renagel, Renvela
Lanthanum carbonate	Forms insoluble phosphate complexes in the gut	Chewable tablets	High potency, low pill burden, works in wide range of pH, no negative effects on bone histology	Unpalatable, GI adverse effects	Fosrenol
Sucroferric oxyhydroxide	A ligand exchange iron-based compound	Chewable tablets	Low pill burden, works in wide range of pH, minimal systemic absorption	Expensive, GI adverse effects, unpalatable	Velphoro
Ferric citrate	Forms insoluble phosphate complexes in the gut	Swallowed tablets	Also serves as a treatment for iron deficiency anemia	Expensive, high pill burden, GI adverse effects, potential for iron overload	Auryxia
Aluminum hydroxide	Forms insoluble phosphate complexes in the gut	Swallowed tablets and liquid	Inexpensive, calcium-free, works in wide range of pH	No safe dose established, cognitive toxicity, osteomalacia (bone toxicity)	AlternaGEL, Amphogel, Nepohrox

Figure 4: Phosphate Binder Mechanisms of Action, Adapted from Covic and Rastogi, 2013.

Despite the commercial availability of the six phosphate binders in the table above, 75% of U.S. dialysis patients fail to achieve the serum phosphorus target levels established by the KDIGO guidelines. Moreover, the percentage of patients achieving these serum phosphorus guidelines is trending downward — underscoring the need for new and effective treatment options (**Figure 5**).



KDOQI: The Kidney Disease Outcomes Quality Initiative

Figure 5: Serum Phosphorus Target Achievement from 2012 to 2021

In 2005, Unruh, ML published a paper that showed poor adherence to treatment is common in patients with ESRD and has been associated with an increased risk of mortality. In addition, poor adherence to phosphate binder therapy has been associated with failure to adequately control serum phosphorus concentrations as shown in a publication by Arenas, MD and others in 2010. Results from a study of 233 patients on maintenance dialysis from three different dialysis units in the U.S. showed that patients took a mean of 11 ± 4 medications with a median daily pill intake of 19 as shown by Chiu, YW in 2009. Phosphate binders accounted for nearly 50% of the total pill burden, with a median daily pill count of nine. Only 38% of patients in this study reported that they were adherent to their prescribed phosphate binder therapy and adherence decreased significantly with increased pill count.

Potential strategies to improve adherence to phosphate binders in patients with ESRD include: (i) a reduction in pill size and number, (ii) improvement of palatability, and (iii) a reduction in associated adverse effects as published in a study by Covic and Rastogi in 2013.

Therefore, we believe there is a current need for better phosphate binders with high phosphate binding capacity, enabling a reduced pill burden for better medication compliance.

By virtue of its novel nanoparticle technology, OLC leverages the high phosphate binding potency of lanthanum in a palatable dose form that has the potential to substantially reduce the pill burden volume for patients. In this regard, we believe that the combined effect of smaller pill size, lower number of pills, and improved palatability with oxylanthanum carbonate compared with currently available phosphate binders may lead to improved patient compliance/adherence and more effective disease management.

Development of Oxylanthanum Carbonate

Oxylanthanum Carbonate Mechanism of Action

Oxylanthanum carbonate binds to phosphates and forms an insoluble lanthanum phosphate complex which is then excreted via the feces. This results in reduced absorption of phosphate leading to a reduction of serum phosphorus levels.

In rat studies, oxylanthanum carbonate exhibited comparable reduction in the urine phosphorus excretion following administration of a lower dose of drug product (0.40g) vs a higher dose (0.57g) of Fosrenol® (lanthanum carbonate tetrahydrate) which is a currently approved lanthanum-based phosphate binder. While differing in the mass of drug product, each dose contained comparable amounts of the active moiety (elemental lanthanum). In the same study, at equivalent doses, Oxylanthanum carbonate was superior to Sevelamer (the most commonly used phosphate binder) in reducing urine phosphorus excretion (see **Figure 6** below).

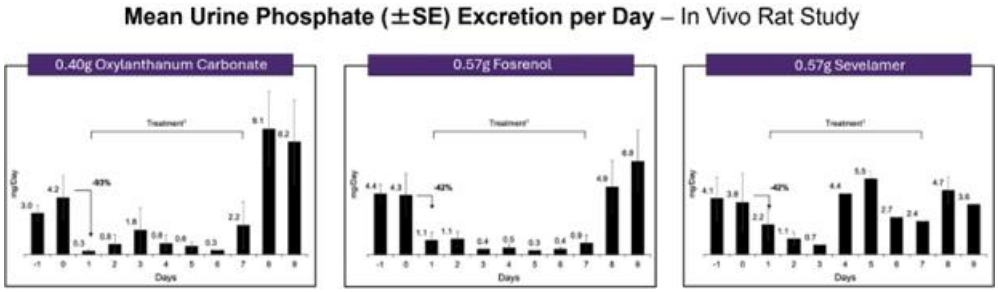


Figure 6: Urine Phosphate Levels in Rats Following Comparable Dosing of Oxylanthanum Carbonate, Fosrenol, or Sevelamer

In animal toxicology studies with oxylanthanum carbonate no unexpected toxicity was found and systemic absorption of lanthanum was extremely low, which is consistent with similar studies conducted with Fosrenol.

The chemical structure of oxylanthanum carbonate was designed to allow for a smaller tablet size and require fewer pills compared with currently available phosphate binder alternatives, specifically with a dosing regimen of only one tablet per meal. The oxylanthanum carbonate tablet is designed to disintegrate rapidly in the stomach after swallowing and does not need to be chewed.

Clinical Trial Experience

Unicycive is seeking FDA approval of OLC via the 505(b)(2) regulatory pathway. The NDA submission package is based on data from three clinical studies: a first in human Phase I study in healthy volunteers, a Bioequivalence (BE) study in healthy volunteers, and a pivotal Phase 2 tolerability study of OLC in CKD patients on dialysis, as well as multiple preclinical studies, and the chemistry, manufacturing and controls (CMC) data.

Pivotal Phase 2 Study

We conducted a Phase 2, open-label, single-arm, multicenter trial in adult patients receiving maintenance hemodialysis with hyperphosphatemia. The primary objective was to evaluate the tolerability of OLC at clinically effective doses with a goal serum phosphate concentration (sP) ≤5.5 mg/dL. The trial included washout, titration, and maintenance periods. Eligible patients had sP ≥4.0 and ≤7.5 mg/dL for at least 8 weeks prior to screening while receiving thrice weekly hemodialysis and a stable phosphate binder regimen. Patients started titration when sP was >5.5 mg/dL and entered maintenance once sP was ≤5.5 mg/dL. The starting dose of OLC during titration was 1500 mg/day (500 mg thrice daily).

In the study, 106 patients were enrolled, of which 86 patients entered titration and were followed as the Safety Population. Of the 86, 78 entered the maintenance period. Of the 78 patients that entered maintenance, 7 patients did not have phosphate control, leaving an Evaluable Population of 71 patients, exceeding the planned enrollment number of 60. Of the 86 patients, the trial enrolled 47 males and 39 females with a mean age of 62. Renvela® was the most prescribed phosphate binder for patients entering the study.

*Primary Endpoint - Tolerability: T*he objective of the OLC-201 trial was to evaluate the tolerability of clinically effective doses of OLC in CKD patients on dialysis. A clinically effective dose was established when a patient achieved a serum phosphate level ≤5.5 mg/dL. Tolerability was assessed based on the incidence of treatment-related AEs leading to discontinuation from the study in the maintenance period. In the OLC-201 trial, there was only 1 discontinuation due to a treatment-related AE in the Evaluable Population, a rate of 1.4%. In the Safety Population of 86 patients there were only 3 treatment-related discontinuations, a rate of 3.5%. In total, 5 patients discontinued due to AEs in the Safety Population, 3 were related to OLC and 2 were deemed unrelated to OLC.

Secondary Endpoint - Safety: The secondary endpoint assessing safety was reported as the treatment-related AEs occurring in ≥5% of patients. The safety analysis covered all 86 patients in the Safety Population. Consistent with the AEs observed with other phosphate binders, the AEs were gastrointestinal related with diarrhea and vomiting being the most common at 9% and 6% respectively. There were no treatment-related serious adverse events (SAEs). Six patients experienced SAEs but those were deemed not related to OLC treatment. Most treatment-related AEs were mild to moderate in severity with only 2 AEs reported as severe. (**Figure 7**)

Treatment-Related Adverse Events in ≥5% Patients

Adverse Event	(N=86) n (%)
Diarrhea	8 (9%)[a]
Vomiting	5 (6%)[a]

a) Two patients experienced both diarrhea and vomiting

Figure 7: OLC Pivotal Phase 2 Trial Treatment-Related Adverse Events

Serum Phosphate Control: While the UNI-OLC-201 study was not designed to evaluate efficacy, the trial enrolled patients on stable doses of approved hyperphosphatemia medications. At baseline 59% of patients had phosphate levels ≤5.5 mg/dL, the level recommended by KDOQI guidelines. After washout from the prior phosphate binders, 90% of patients were able to achieve phosphate levels ≤5.5ng/dL at the end of titration with OLC. This includes the last serum phosphate levels from all patients including those that discontinued during titration: 77/86 (90%) (**Figure 8**). In addition, 69% of the 71 Evaluable Patients achieved a target serum phosphate level of ≤5.5 mg/dL at OLC doses of 1500 mg/day or lower. (**Figure 9**)

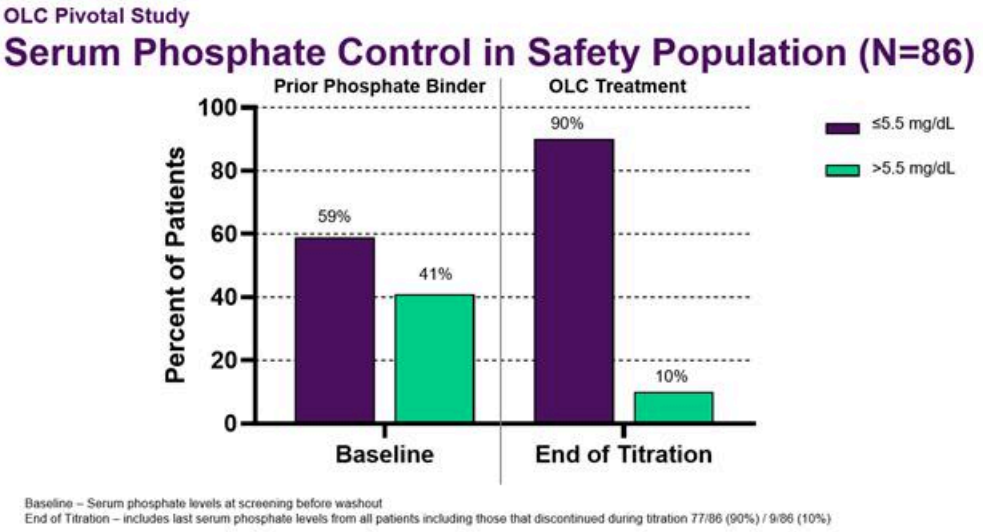


Figure 8: 90% Of Patients Were Able to Achieve Phosphate Levels ≤5.5ng/dL with OLC.

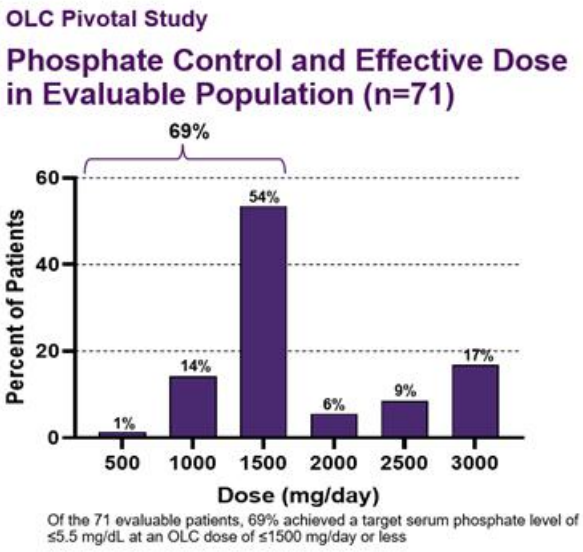


Figure 9: 69% of the 71 Evaluable Patients Achieved a Target Serum Phosphate Level of ≤5.5 mg/dL at OLC Doses of 1500 mg/Day or Lower

First-in-Human Phase 1 Study

In September 2012 a Phase 1 single-center clinical trial evaluating oxylanthanum carbonate in 32 healthy volunteers was completed in the United States. Four sequential dose cohorts of 8 subjects each (6 actives and 2 placebos) received oxylanthanum carbonate at 1500, 3000, 4500, or 6000 mg/day, taken orally in 3 divided doses within 15 minutes after meals, for five consecutive days. The primary endpoint of the study was the evaluation of safety, and the secondary endpoint was the phosphate binding capacity of oxylanthanum carbonate as judged by the level of phosphorus in feces and urine. We believe the study indicated that oxylanthanum carbonate was minimally absorbed to the systemic circulation and was well-tolerated at doses up to 6000 mg/day. oxylanthanum carbonate significantly reduced urine phosphate excretion and significantly increased fecal phosphate excretion at doses at and above 3000 mg/day. The mean overall change in phosphorus from baseline in both urine and feces, across all treatment groups, showed a dose-response trend that was statistically significant ($p<0.0001$ and $p=0.0004$, respectively). The mean reduction in urine phosphorus excretion was not significant at 1500 mg/day ($p=0.3676$) but was significant at 3000 ($p=0.0004$), 4500 ($p<0.0001$), and 6000 ($p=0.0001$) mg/day, as shown in the figure below.

The mean reduction in urine phosphorus excretion was significant ($p<0.001$) at all four doses of oxylanthanum carbonate (**Figure 10**).

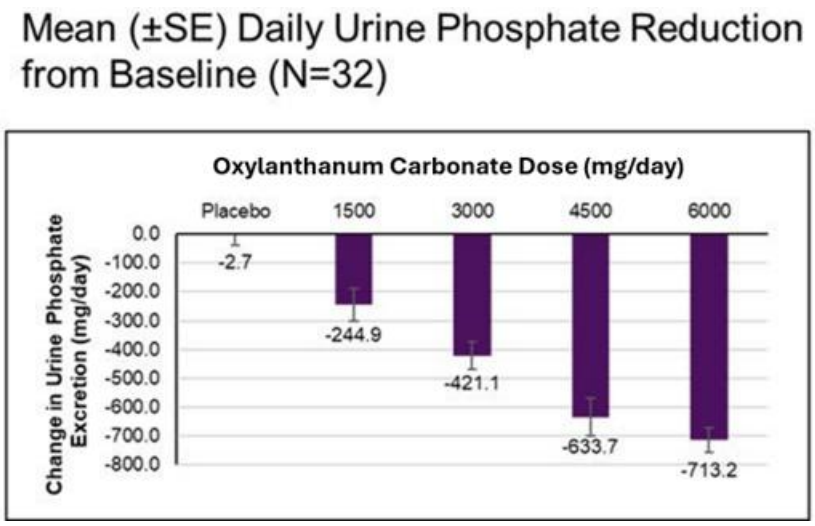


Figure 10: Daily Urine Phosphate Reduction in Healthy Volunteers

Oxylanthanum Carbonate Bioequivalence Study in Healthy Volunteers

We conducted a randomized, open label, two-way crossover bioequivalence BE study to establish the bioequivalence of the phosphate binding capacity of oxylanthanum carbonate and Fosrenol. The primary objective of the study was to demonstrate PD equivalence of orally administered oxylanthanum carbonate 1000 mg three-times daily (TID) to orally administered Fosrenol 1000 mg TID in healthy subjects, and the secondary objective was to compare the safety and tolerability of oxylanthanum carbonate versus Fosrenol in healthy subjects. The study design, including the dose, primary endpoint and the sample size was reviewed by the Agency prior to the initiation of the study. The primary outcome measure was least squares (LS) mean change in urinary phosphorous excretion (in mg/day) from baseline to the evaluation period. The evaluation period was defined as the approximately 72-hour urine collection period starting on Day 1 and ending on Day 4. Baseline was defined as the approximately 48-hour urine collection period starting on Day -2 and ending on Day 1. PD equivalence was to be claimed if the 90% confidence interval (CI) of the primary PD variable for oxylanthanum carbonate was completely contained within the reference interval, which was defined as ±20% of the LS mean of the primary PD variable for lanthanum carbonate. The LS mean change from Baseline for oxylanthanum carbonate (-320.4 mg/day) was similar to the LS mean change from Baseline for Fosrenol (-324.0 mg/day). The 90% CI for the LS mean was (-37.83, 45.12), which is well within the acceptance range of (-64.80, 64,80). It was concluded that oxylanthanum carbonate was bioequivalent to Fosrenol. Primary outcome data is presented in the table below (**Figure 11**).

Visit	Statistics	Phosphorus Excretion (mg/day)	
		OLC (N=75)	Fosrenol (N=75)
Baseline	LS Mean, mean (SE)	861.6 (30.90)	876.1 (30.90)
Evaluation Period	LS Mean, mean (SE)	546.7 (19.36)	546.8 (19.36)
Change from Baseline	LS Mean Change	-320. 4 (17.71)	-324. 0 (17.71)
	90% Confidence Interval for the LS mean (Test-Reference)	(-37.83, 45.12)	
	Acceptance Range	(-64.80, 64.80)	

Figure 11: Summary of Mean Change in Urinary Phosphorus Excretion (mg/day)

Regulatory Guidance

We are seeking approval for oxylanthanum carbonate from the U.S. Food and Drug Administration (FDA) through the 505(b)(2) regulatory pathway. The 505(b)(2) pathway allows for full approval of a drug using data from an approved drug with the same active moiety. The approved drug is called the Reference Listed Drug (RLD). The RLD for the oxylanthanum carbonate submission is Fosrenol (lanthanum carbonate). The FDA recommended conducting a BE study in healthy volunteers and a 6-month toxicity study in mice with both oxylanthanum carbonate and Fosrenol to be able to rely on the efficacy and safety of Fosrenol. We completed both studies and submitted the data for the FDA's review during the pre-NDA (New Drug Application) meeting request. After reviewing the data, the Agency recommended that we conduct a tolerability study of oxylanthanum carbonate in chronic kidney disease patients on dialysis before filing the NDA. We gained alignment with the FDA on the study design, sample size, and endpoints of the proposed pivotal clinical study during a Type-C meeting in September 2023. This study was initiated in December 2023 and reported positive results in June 2024. We announced the OLC NDA submission in September 2024 and received a PDUFA date of June 28, 2025. In June 2025 the FDA issued us a Complete Response Letter (CRL) notifying us that a third-party manufacturing vendor of its main contract development and manufacturing organization (CDMO) was cited for deficiencies following a cGMP inspection. No other concerns have been identified to the Company, including pre-clinical, clinical, or safety data submitted as part of the NDA. In October 2025 we held a Type A meeting with the FDA to discuss the resolution of the single deficiency identified in the CRL related to the compliance status of a third-party manufacturing vendor. Following receipt of the official meeting minutes from the Type A meeting and engaging in discussions with its third-party manufacturing vendor, we resubmitted its NDA to the FDA in December 2025. In January 2026, the FDA accepted the resubmission of the NDA for OLC, deeming the resubmission to be a Class II complete response which has a six-month review period from the date of resubmission, and set a PDUFA) target action date of June 29, 2026.

U.S. Commercial Opportunity for Oxylanthanum Carbonate

Overview

Unicycive Therapeutics is a biopharmaceutical company dedicated to developing and commercializing innovative therapies for patients with kidney disease. Our lead product candidate, oxylanthanum carbonate (OLC), is a next-generation, orally administered, non-calcium-based phosphate binder being developed for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis.

We are transitioning from a clinical-stage organization to a commercial-stage company in anticipation of the potential U.S. approval and launch of OLC. Our strategy is to establish OLC as a differentiated therapy within the hyperphosphatemia treatment paradigm while building a focused nephrology franchise supported by disciplined commercial execution and capital-efficient infrastructure.

Our commercial organization is led by executives with significant expertise in nephrology and dialysis markets. Members of our leadership team have extensive experience launching and managing renal franchises, including navigating the Medicare End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), contracting with dialysis organizations, and executing within highly concentrated provider environments.

Our objective is to combine a differentiated clinical profile, a concentrated go-to-market model, and a strategically aligned reimbursement approach to support meaningful adoption of OLC.

Commercial Strategy: Oxylanthanum Carbonate (OLC)

U.S. Market Opportunity and Unmet Need

Hyperphosphatemia is a near-universal complication among the approximately 550,000 dialysis patients in the United States. Elevated serum phosphorus levels are associated with secondary hyperparathyroidism, renal bone disease, vascular calcification, and increased cardiovascular morbidity and mortality. Effective phosphate management is therefore a foundational component of dialysis care.

Approximately 80% of dialysis patients are prescribed phosphate-lowering therapies (PLTs), representing a total addressable U.S. market of more than 440,000 patients. The global market for hyperphosphatemia therapies is estimated to be approximately $2.5 billion annually, with the U.S. market accounting for more than $1 billion.

Despite multiple available therapeutic options, significant unmet need persists:

- Pill Burden: Standard-of-care binders often require patients to ingest up to 10–12 tablets daily. Dialysis patients are commonly prescribed numerous additional medications to manage anemia, mineral bone disorder, and cardiovascular comorbidities, resulting in substantial cumulative pill burden and treatment fatigue.

- Tolerability and Administration Challenges: Existing binders are frequently associated with gastrointestinal (GI) side effects. Certain lanthanum and iron-based therapies (Velphoro – sucroferric oxyhydroxide and Fosrenol – lanthanum carbonate) require chewable administration of large, chalky tablets, which may impact palatability and persistence with long-term therapy.

- Suboptimal Phosphorus Control: A substantial proportion of U.S. dialysis patients fail to consistently achieve recommended phosphorus targets. Non-adherence and dose reductions due to tolerability are commonly cited contributors with 44-75% of U.S. dialysis patients failing to achieve target phosphorus levels established by published clinical practice guidelines.

Because dialysis patients require chronic, lifelong phosphate management, therapies that improve ease of administration and reduce pill burden may have important clinical and economic implications.

Our Solution: Oxylanthanum Carbonate (OLC)

OLC is designed to address limitations of current phosphate binders through a proprietary formulation intended to combine potency with reduced medication volume.

We believe OLC offers the following potential advantages:

- High Potency-to-Volume Ratio: Designed to achieve phosphorus control with a lower daily pill burden compared to commonly prescribed binders.
- Swallowable Tablet: Unlike currently marketed iron and lanthanum-based therapies that require chewable administration, OLC tablets are designed to be swallowed whole.
- Calcium-Free Composition: Avoids calcium exposure associated with certain legacy therapies.
- Flexible Positioning: May be used as monotherapy or, where clinically appropriate, in combination regimens for patients requiring additional control.

By directly addressing pill burden and administration challenges, OLC is intended to improve patient experience and potentially support adherence within this chronic treatment population.

Commercial Readiness and Organizational Development

Leadership and Talent

We have recruited a commercial leadership team with deep nephrology experience, including prior hyperphosphatemia launches and dialysis organization contracting expertise. Our embedded commercial team includes Marketing, Market Access, Medical Affairs, Professional Relations, and Commercial Operations functions.

These teams maintain established relationships with key opinion leaders (KOLs), high-volume prescribers, and dialysis organization decision-makers.

Market Development Activities

During OLC pre-launch market development, our teams have:

- Conducted advisory boards with nephrology key opinion leaders (KOLs) and primary market research
- Participated in major nephrology conferences
- Published and presented OLC-related clinical data
- Engaged with dialysis organizations regarding clinical and economic considerations

Commercial Operations Infrastructure

Throughout 2025 and early 2026, we have significantly accelerated our commercial readiness activities to support the pending U.S. approval and launch of OLC. We have evolved from a development-led organization into a launch-ready commercial enterprise by establishing the relevant infrastructure and systems to support our commercial teams.

- Advanced CRM systems
- Data analytics platforms for physician segmentation
- Compliance frameworks and internal controls
- Medical information and pharmacovigilance systems
- Scalable supply chain and logistics infrastructure

Targeted Sales and Account Management

Our market analysis indicates that the U.S. nephrology market is highly concentrated. While there are more than 10,000 total prescribers of phosphate lowering therapies (PLTs), our data shows that the approximately 2,100 highest prescribers are responsible for half of the prescriptions written for PLTs annually.

- Specialty Sales Force**:** We intend to address this concentrated market through a lean, highly technical specialty sales force that will target the most productive segments of PLT market.
- Digital & Non-Personal Promotion: We are leveraging AI technology to reach the broader prescriber base efficiently, through an omnichannel digital strategy to extend our OLC promotion and medical education campaigns.
- Strategic Dialysis Partnerships: Given the consolidated nature of the U.S. dialysis market, we are prioritizing engagement with large Dialysis Organizations (LDOs) and mid-sized dialysis organization to ensure OLC is integrated into clinical protocols and institutional formularies.

Dialysis Market Concentration

The U.S. dialysis market is highly consolidated. A limited number of dialysis organizations treat the substantial majority of the approximately 550,000 U.S. dialysis patients.

Dialysis Organization	Approx. U.S. Patients	Cumulative % of U.S. Dialysis Population
DaVita Inc.	~200,800	~37%
Fresenius Kidney Care	~190,000	~71%
U.S. Renal Care (including Satellite-administered network)	~37,000	~78%
Dialysis Clinic, Inc. (DCI)	~15,000	~81%
Innovative Renal Care	~16,000	~85%

The source is: The National Forum of ESRD Networks. Quarterly National ESRD Census www.esrdnetworks.org

Collectively, these organizations influence treatment decisions for approximately 85% of U.S. dialysis patients through centralized medical leadership, formulary governance, group purchasing organizations, and aligned specialty pharmacy networks.

Because oral-only phosphate binders are reimbursed within the ESRD PPS bundled payment for Medicare beneficiaries, dialysis organizations play a meaningful role in therapy adoption decisions. Successful contracting, formulary positioning, and clinical protocol integration within a limited number of dialysis organizations may therefore provide access to a substantial majority of bundled Medicare dialysis patients.

This concentrated structure enables a focused and capital-efficient commercial strategy centered on high-volume prescribers and key dialysis accounts.

Distribution and Logistics

We have established a streamlined and capital-efficient distribution model designed to support broad and reliable access to OLC shortly following FDA approval.

- Channel Strategy: We are entering into agreements with a limited number of national specialty distributors and wholesalers. These partners will manage the physical distribution of OLC to the pharmacies designated by prescribers and dialysis organizations, including LDO-owned specialty pharmacies and independent providers.

- Third-Party Logistics (3PL): We have engaged a third-party logistics provider to manage our inventory, warehousing, and order-to-cash processes. This allows us to scale our commercial footprint rapidly upon FDA approval without the capital-intensive requirement of building a proprietary physical distribution network.

Market Access and Reimbursement Strategy

Phosphate Lowering Therapies (PLTs) Payer Mix

Phosphate-lowering therapies are reimbursed through two primary pathways:

- Bundled Medicare (~65% of patients): Includes Medicare Fee-for-Service and Medicare Advantage beneficiaries treated under the ESRD PPS bundled payment.

- Unbundled / Traditional Payers (~35% of patients): Includes commercial insurance, managed Medicaid, and state Medicaid programs where therapies are reimbursed under the pharmacy benefit.

Supporting OLC Market Access for Non-Medicare Patients

We intend to establish UniSource™, a comprehensive reimbursement support program designed to facilitate access for patients covered under commercial and Medicaid plans. UniSource™ will provide the following high-touch, friction-minimizing reimbursement support to providers and patients:

- Benefit investigations
- Prior authorization and appeals support
- Co-pay assistance programs for eligible commercially insured patients
- Patient assistance programs for uninsured or underinsured patients

Navigating the Bundled Medicare Reimbursement Environment

Over two thirds of our target patient population is covered by Medicare. Effective January 1, 2025, CMS transitioned oral-only phosphate binders into the ESRD PPS bundled payment. To promote innovation within the bundle, CMS provides the Transitional Drug Add-on Payment Adjustment (TDAPA). If OLC receives FDA approval, we intend to apply for TDAPA.

If granted, TDAPA would provide separate reimbursement for OLC at 100% of Average Sales Price (ASP), for a two-year period.

Following the initial 2-year TDAPA period, CMS has established a transitional risk-sharing adjustment under which dialysis organizations may receive an additional payment equal to 65% of incremental costs above the bundled rate during a defined transition period of 3 years.

The TDAPA period applicable to certain existing phosphate binders is expected to conclude at the end of 2026, after which CMS is expected to incorporate related expenditures into a rebased ESRD PPS bundled rate. If OLC receives approval and is granted TDAPA with an anticipated first-half 2027 launch, OLC may be the only phosphate binder eligible for separate reimbursement during its TDAPA period. In such a scenario, dialysis organizations could receive both rebased bundle payments reflecting prior phosphate binder utilization and separate reimbursement for OLC during its separate TDAPA period. We believe this dynamic may create a favorable economic framework for rapid evaluation and adoption of OLC.

Congressional legislation currently under consideration, the Kidney Care Access Protection Act (KCAPA), proposes potential enhancements to TDAPA duration (from 2 to 3 years) and post-TDAPA payments (from 3 years to perpetuity) which may substantially expand the revenue potential for OLC. We cannot predict whether such legislation will be enacted.

Competition

The market for hyperphosphatemia treatments is highly competitive and characterized by a well-established standard of care. Our potential competitors include biopharmaceutical innovators and generic companies that market calcium-based binders, non-calcium-based binders, and novel phosphate absorption inhibitors.

Current Landscape and Limitations of Standard of Care

Existing therapies are often limited by significant patient hurdles, primarily high pill burden and poor gastrointestinal (GI) tolerability. Standard-of-care binders, such as sevelamer carbonate, often require patients to ingest up to 10–12 large tablets daily. This “pill fatigue” contributes to low adherence, with studies suggesting a significant portion of dialysis patients fail to achieve target phosphorus levels.

Primary Competitors

Category	Leading Products	OLC Competitive Advantage
Non-Calcium Binders	*Renvela®/Renagel® (sevelamer), Fosrenol® (lanthanum carbonate)*	OLC offers a significantly lower pill burden and avoids the need for chewable administration.
Iron-Based Binders	*Velphoro®, Auryxia®*	OLC avoids potential iron-overload concerns and offers a more favorable volume-per-dose profile.
Absorption Inhibitors	*Xphozah® (tenapanor)*	While tenapanor offers a novel mechanism, OLC remains a potent binder that can be used as monotherapy or potentially in combination with tenapanor.
Calcium Binders	*PhosLo® (calcium acetate)*	OLC is calcium-free, avoiding the risk of vascular calcification associated with long-term calcium-based therapy.

Figure 12: *Primary competitors of OLC*

Our Competitive Advantage: Oxylanthanum Carbonate (OLC)

We believe OLC is positioned to disrupt the current treatment paradigm through its proprietary formulation, which offers:

- Superior Potency-to-Volume Ratio: OLC is designed to provide high phosphate-binding capacity with a significantly lower daily medication volume compared to sevelamer and other metallic binders.
- Improved Patient Experience: Unlike many existing binders that must be chewed (e.g., lanthanum carbonate/Fosrenol), OLC tablets are designed to be swallowed whole, addressing a common patient aversion to the chalky taste and dental issues associated with chewable tablets.
- Optimized for Patient Adherence: By reducing the total number of pills required to achieve target levels, OLC directly addresses the primary driver of non-adherence in the dialysis population.

Global Strategy and Strategic Partnerships

We retain full global commercial rights to OLC, except in certain territories where we have established strategic licensing partnerships.

In Greater China, we have licensed rights to Lee's Pharmaceutical Holdings Limited, which is responsible for regulatory approval and commercialization within the territory. In select Asian markets, we have entered into a licensing agreement with Lotus Pharmaceutical Co., Ltd., which is responsible for regulatory filings, commercialization, and distribution within its designated regions. Under these agreements, we are eligible to receive milestone payments and tiered royalties on net sales.

These partnerships allow us to leverage established regional infrastructure while preserving capital and maintaining strategic focus on the U.S. market.

While our primary near-term focus is a self-directed U.S. launch of OLC, we continue to evaluate complementary strategies, including potential co-promotion or distribution partnerships, where such arrangements may enhance market penetration and long-term franchise value.

Strategic Vision

We view OLC as the foundation of a focused nephrology franchise. By leveraging our dialysis relationships, reimbursement expertise, and commercial infrastructure, we aim to establish a durable presence in the renal therapeutic landscape and evaluate additional complementary opportunities over time

Manufacturing

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. If and when any of our product candidates are approved, we plan to obtain manufacturing capacity through contract manufacturing organizations (CMOs) to meet projected needs for commercial sale quantities and serve patient needs.

With regards to manufacturing, testing and potential commercial supply of oxylanthanum carbonate, on October 31, 2020, the Company entered into an agreement with Shilpa Medicare Ltd ("Shilpa") based in India. Pursuant to the Agreement, Shilpa provides certain development, manufacturing, supply and other CMC-related services related to the development and commercialization of oxylanthanum carbonate ("OLC").

In June 2024, we entered into the First Amendment to Manufacturing and Supply Agreement with Shilpa (the "Amendment") in anticipation of an increased manufacturing demand for OLC. Pursuant to the Amendment, we agreed to make a binding purchase order for tablets of OLC and Shilpa has agreed to deliver such order by September 30, 2025. In addition, we agreed to order additional tablets for delivery between December 31, 2025, and September 30, 2026. Further, we agreed to make certain milestone payments and to provide certain funding to Shilpa for a new manufacturing line. The initial term of the Agreement shall continue until the eighth (8th) anniversary of the date of receipt by us of FDA approval of our NDA of OLC (the "Initial Term"). Following the Initial Term, the Agreement shall continue in effect for consecutive periods of four (4) years each unless earlier terminated pursuant to the terms of the Agreement.

Oxylanthanum Carbonate Purchase Agreement

On September 20, 2018, we entered into an Assignment and Asset Purchase Agreement (the "Spectrum Agreement") with Spectrum Pharmaceuticals, Inc. ("Spectrum"), pursuant to which we purchased certain assets from Spectrum, including Spectrum's right, title, interest in and intellectual property related to oxylanthanum carbonate RZB 012, also known as RENALAN™ ("Renalan") and RZB 014, also known as SPI 014 ("SPI" and together with Renalan, the "Compounds"). Pursuant to the Spectrum Agreement, in consideration for the Compounds, we issued 313,663 shares of common stock to Spectrum.

Additionally, the Spectrum Agreement provides that until the earlier of (i) 36 months from the first date on which our stock trades on a public market, or (ii) the date upon which we attain a public market capitalization of $50,000,000 or greater, we are required to issue additional shares of our common stock as may be needed to ensure Spectrum maintains a 4% ownership of our issued and outstanding common stock on a fully-diluted basis. Fully-diluted shares of common stock for purposes of the Spectrum Agreement assumes conversion of any security convertible into or exchangeable or exercisable for common stock or any combination thereof, including any common stock reserved for issuance under a stock option plan, restricted stock plan, or other equity incentive plan approved by the Board of Directors of the Company immediately following the issuance of additional shares of our common stock (but prior to the issuance of any additional shares of common stock to Spectrum). We are also required to pay Spectrum 40% of all of our sublicense income for any sublicense granted to certain sublicensees during the first 12 months after the Closing Date (as that term is defined in the Spectrum Agreement) and 20% of all other sublicense income. Our payment obligations to Spectrum will expire on the twentieth (20^{th}) anniversary of the Closing Date of the Spectrum Agreement.

UNI-494

Disease Overview: Acute Kidney Injury (AKI)

Acute kidney injury (AKI) is defined as a sudden loss of kidney function that is diagnosed by increased serum creatinine levels and decreased urine output and is limited to a duration of 7 days, whereas chronic kidney disease (CKD) is defined as persistent decrease in kidney function beyond 90 days. Thus, AKI and CKD can form a continuum whereby initial kidney injury can lead to persistent renal injury, eventually leading to CKD.

Acute kidney injury (AKI) is estimated to occur in approximately 20–200 per million population in the community, 7–18% of patients in hospital, and approximately 50% of patients admitted to the intensive care unit (ICU). Importantly, AKI is associated with morbidity and mortality; AKI affects 13 million people worldwide, and an estimated 2 million people die of AKI every year, whereas AKI survivors are at increased risk of developing chronic kidney disease (CKD) and end-stage renal disease (ESRD) — conditions that carry a high economic, societal, and personal burden (Chawla et al., Nature Reviews-Nephrology, 2017).

Delayed Graft Function (DGF)

Our initial target indication for UNI-494 is delayed graft function. DGF refers to the acute kidney injury that occurs in the first week after kidney transplantation, which necessitates dialysis intervention. Ischemia/reperfusion injury (IRI) is known to be a major risk factor for the AKI that results in DGF. Patients who experience DGF have an increased risk of mortality that's 59% higher than those without DGF. Patients with DGF are also more than 2 times more likely to be readmitted to the hospital within 30-days post-transplantation and are at 41% increased risk of long-term graft loss. Given the average cost of a kidney transplant of nearly $500,000, the economic implications of graft failure due to DGF are staggering.

The potential commercial opportunity for UNI-494 in DGF is substantial. In the US, 46,630 kidney transplants were performed in 2023. This number would undoubtedly be higher were more donor organs available. Currently, there are over 80,000 Americans on the waitlist for a donor kidney. 15% of transplanted kidneys come from living donors meaning that the remaining 85% of donor organs come from deceased donors. While the incidence of DGF is relatively small (1.6 -3.6%) for living donor organs, the risk is considerably higher for deceased donor organs. The rate of DGF is 20 - 30.4% for DBD (donor brain death) organs and 45 – 55.1% for DCD (donor circulatory death) organs. Due to the shortage of donor kidneys and the size of the kidney transplant waitlist, the incidence of DGF is expected to increase as lower quality organs are transplanted.

Treatment of Delayed Graft Function and Acute Kidney Injury

Currently there are no FDA approved medicines to treat DGF and/or AKI. Treatment options for AKI include continuous renal replacement therapy, renal transplant, and dialysis. In most cases the damage to the kidney is irreversible, and the patient needs to have a renal transplant or be on dialysis for life. Therefore, there is a high unmet medical need. If approved, UNI-494 has the potential to be a first-in-class drug for the treatment of AKI.

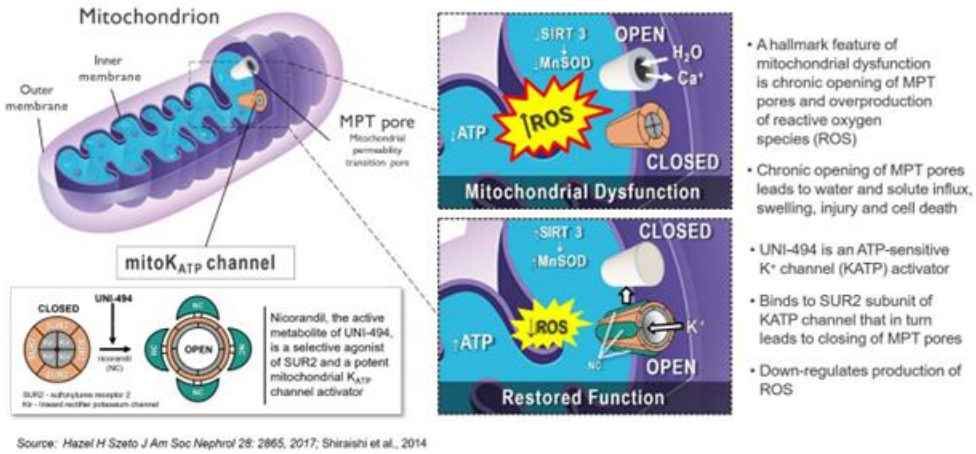
UNI-494: A Novel Prodrug of Nicorandil

Nicorandil, marketed in such products as Ikorel and Dancor, is indicated for the treatment of chronic stable angina pectoris. It is not currently approved in the United States but has been approved for use in Australia, the United Kingdom and most of Europe, and in India, Japan, South Korea, and Taiwan. Nicorandil is a dual-action mitochondrial potassium (mitochondrial K_{ATP}) channel activator and nitrate-like vasodilator. Activation of mitochondrial K_{ATP} channel leads to restoration of mitochondrial function and cytoprotection. Nicorandil has extensive safety and efficacy data from multiple clinical trials, including a 5,000-patient randomized controlled trial (IONA Study, Lancet 2002) and there is a consensus in the literature that the activation of mitochondrial K_{ATP} channel is the biological basis for the observed cardio-protection and reno-protection in multiple clinical trials. Although nicorandil is known to be safe, gastrointestinal ulceration is a rare but severe side effect and it is dose-dependent.

UNI-494 was rationally designed to be absorbed into the systemic circulation, and once absorbed, to release nicorandil into the bloodstream. By avoiding direct exposure to the gastrointestinal tract of nicorandil, it is believed that UNI-494 may be able to minimize or avoid the gastrointestinal side effects of nicorandil. Also, based on the rate of conversion of UNI-494 to nicorandil in the systemic circulation, UNI-494 may offer greater and/or more prolonged exposure to nicorandil for the treatment of patients with acute kidney injury. Our technology for UNI-494 is licensed from Sphaera Pharmaceutical Private Limited, a Singapore-based company ("Sphaera"), with offices in India and the U.S. We have the global, exclusive license to UNI-494. Sphaera conceived of and performed initial characterization of various potential pro-drug linkers, including the initial patent application, and performed some initial physiochemical characterization and preliminary animal pharmacokinetic studies.

Mechanism of Action of UNI-494

UNI-494 is a novel proprietary drug that selectively binds to the SUR2B subunit of the mitochondrial K_{ATP} channel and activates it to restore mitochondrial function and reduce oxidative stress. UNI-494 is cleaved by esterase enzymes to form nicorandil, the active metabolite. The proposed mechanism of action of UNI-494 is shown in **Figure 13** below:



Source: Hazel H Szeto J Am Soc Nephrol 28: 2865, 2017; Shiraishi et al., 2014

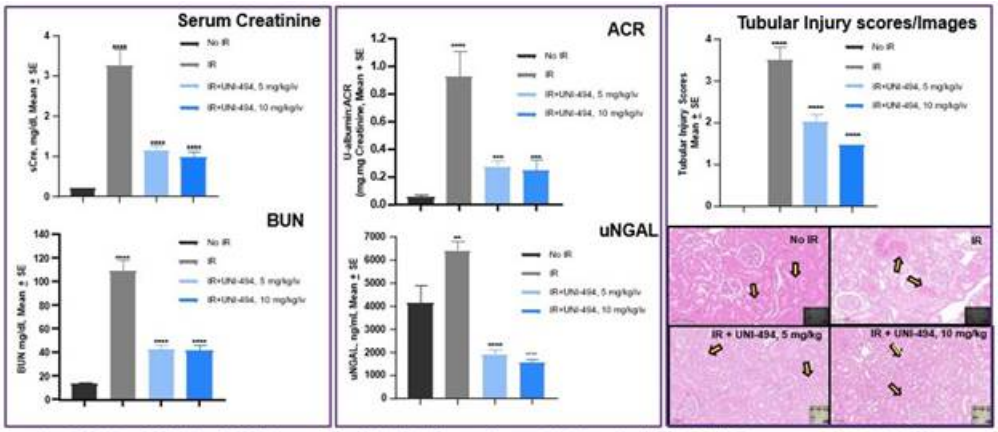
Figure 13: Mechanism of Action of UNI-494

Ischemia/reperfusion injury (IRI) is one of the main reasons for causing acute kidney injury (AKI) that results in DGF during kidney transplantation. Ischemic preconditioning, that works by activating K_{ATP} channels in mitochondria, is a natural endogenous mechanism which protects cells from IRI in the heart, kidney, liver, and other organs. UNI-494 is a pharmacological approach that emulates and enhances this natural phenomenon of ischemic preconditioning.

Rationale for Development

Efficacy of UNI-494 in Animal Models: We conducted pre-clinical pharmacology studies to evaluate the efficacy of UNI-494 in preventive mode on kidney injury with a special focus on kidney functional markers (serum creatinine [sCr], blood urea nitrogen [BUN], and urinary albumin/creatinine ratio [ACR]), tubular injury markers (urinary neutrophil gelatinase-associated lipocalin [NGAL]), and proximal tubular damage (proximal tubular injury scores via histology). The study evaluated the *in vivo* efficacy of intravenous UNI-494 in the unilateral renal ischemia-reperfusion rat model of acute kidney injury, which is a well-established model of DGF.

UNI-494 was administered 30 minutes prior to the induction of ischemia, IR induced significant increases of sCr, BUN, ACR, NGAL, β2-MG, and proximal tubular injury damage scores in the vehicle treated DGF group when compared to No DGF sham group ($p<0.0001$ – as per one-way ANOVA multiple comparison test). Following treatment with UNI-494, there was a statistically significant reduction of biomarkers and improvement in tubular injury as shown below in **Figure 14**:



**p = 0.01; ***p = 0.001; ****p = 0.0001 when compared to No IR or IR group; Arrows pointed to proximal tubule; Tubular Scores as per Jablonski et al 1983

Figure 14: Effect of UNI-494 on Ischemia-Reperfusion Injury in Rats

Importantly, UNI-494 prevented serum and urinary markers of AKI at 5 mg/kg, and proximal tubular injury scores improved in a dose-dependent manner. The study concluded that UNI-494 is a potential candidate for prevention of DGF and other AKI clinical conditions.

UNI-494 Clinical Development Status

We have completed a Phase I study in healthy volunteers to evaluate the safety and tolerability of UNI-494.

Phase I Study in Healthy Volunteers

The Phase 1 study was a single center, double-blind, placebo-controlled, randomized single ascending dose (Part 1) and multiple ascending dose (Part 2) study in healthy volunteers conducted in the United Kingdom. Dosing in both arms was completed in a stepwise fashion. The objective of the study was to assess the safety, tolerability and pharmacokinetics of UNI-494.

Single Ascending Dose: Part 1 of the study enrolled 40 participants in 5 cohorts with 30 participants dosed with UNI-494 and 10 participants dosed with placebo. UNI-494 was well-tolerated in healthy participants as a single dose ranging from 10 mg to 160 mg. There were no serious adverse events (SAEs) or adverse events (AEs) leading to withdrawal. Headache was the most common adverse event reported. Most of the adverse events were mild, and all participants dosed with UNI-494 completed the study.

Multiple Ascending Dose: Part 2 of the study enrolled 19 participants in two cohorts with 15 participants dosed with UNI-494 and 4 dosed with placebo. In Cohort One (n=9), participants were dosed with 40 mg two times a day (BID) for 5 days with UNI-494 or matching placebo. In Cohort Two (n=10), participants were dosed with 80 mg BID for 5 days. There were no serious adverse events (SAEs) in Part 2 of the study, and UNI-494 was safe and well-tolerated at the 40 mg BID dose for 5 days. Most common adverse events reported included headache, nausea, and vomiting. In Cohort One, the majority of the adverse events reported were mild and all but one participant completed the study. In Cohort Two, UNI-494 was not well-tolerated with 4 participants withdrawing from the study due to adverse events.

Pharmacokinetics of UNI-494 were also evaluated in the study. The absorption of UNI-494 was fast, and UNI-494 was rapidly metabolized to release nicorandil and the linker as expected.

Following the completion of Phase I study in healthy volunteers, we requested a meeting with the FDA to discuss our proposed clinical study in patients undergoing kidney transplantation. This study is designed to evaluate the safety and tolerability of UNI-494 in patients undergoing kidney transplantation and to get proof of concept data on the efficacy of UNI-494 to prevent DGF. In a written response, the FDA recommended additional studies before a clinical study is initiated in patients undergoing kidney transplantation. Based on the feedback from the FDA, and our current focus on commercializing and launching our lead drug, OLC, the company decided to deprioritize further development of UNI-494 for the time being.

Regulatory Strategy for UNI-494

Orphan Drug Designation: In February 2024, the FDA granted orphan drug designation to UNI-494 for prevention of DGF in patients undergoing solid organ transplantation. The FDA, through its Office of Orphan Products Development (OOPD), grants orphan drug designation to drugs that have the potential to offer a safe and effective treatment, diagnosis or prevention of rare diseases that affect fewer than 200,000 patients in the United States. Orphan drug designation provides certain benefits to the drug developer that include the following: 1) tax credits for qualified clinical trials, 2) exemption of user fees and 3) potential for seven years of market exclusivity after approval.

The FDA issued a guidance to industry in 2019 for development of drugs for prevention of DGF in kidney transplantation. This guidance outlines the study design, patient population, randomization, stratification, dose selection and primary endpoints required for registration of drugs in DGF. This guidance provides a clear path for development of drugs for prevention of DGF.

Nicorandil is already approved in Europe and Asia for the treatment of heart disease. We believe there is a possibility these historical Nicorandil data, along with preclinical and clinical data with UNI-494 itself, can be utilized for streamlined U.S. FDA review of UNI-494. While the pre-clinical requirements to start a clinical program for an IND would be similar for UNI-494 as for NCE (New Chemical Entity), we believe that the vast clinical data set from Nicorandil will potentially help us to expedite the clinical development program with the FDA.

Market Potential

In Delayed Graft Function (DGF): A UNI-494 per patient treatment cost of $25,000 for the ~40,000 deceased donor kidney transplants per year values the DGF market at $1 billion. This estimate of the DGF market potential is only intended to be illustrative. The commercial potential of UNI-494 will be determined by the portion of the market ultimately addressable by UNI-494 and its actual launch price. Given the economic consequences of kidney graft failure, a clinically effective UNI-494 could reasonably command a significantly higher market price.

In Acute Kidney Injury (AKI): According to a 2017 article by Silver and Chertow, the current cost of care for AKI in the U.S. is estimated to be between $5.4 billion to $24 billion per year. In England, inpatient costs related to AKI are estimated to make up 1% of the total National Health Service budget. With no effective treatment for AKI, it is not possible to definitively state a market figure. However, with the high cost and burden of caring for AKI patients, we believe a conservative market estimate is approximately $3 billion in the U.S. alone. The lack of effective therapeutic interventions for AKI means that UNI-494 has the potential to be the first drug approved for the treatment of AKI. AKI is a heterogeneous disease. We plan to target a more homogeneous AKI population for UNI-494 by focusing on kidney injury caused by complications from heart failure, surgeries, drugs, and contrast induced nephropathy.

Sphaera License Agreement

On October 1, 2017, we entered into an exclusive license agreement (the "Sphaera License Agreement") with Sphaera Pharma Pte. Ltd., a Singaporean pharmaceutical corporation ("Sphaera"). Pursuant to the Sphaera License Agreement, we acquired an exclusive royalty-bearing global license to develop, make, have made, use, practice, research, distribute, lease, sell, offer for sale, license, import or otherwise dispose of certain rights owned or controlled by Sphaera and/or any of its affiliates, related to UNI-494 (the "UNI-494 Rights"). We also acquired a non-exclusive license to certain know-how and technology related to the UNI-494 Rights. Sphaera conceived of and performed initial characterization of various potential pro-drug linkers, including the initial patent application, and performed some initial physicochemical characterization and preliminary animal pharmacokinetic studies.

Under the terms of the Sphaera License Agreement, we are obligated to pay to Sphaera, on a quarterly basis, a running royalty of 2% of our net sales (including our affiliates) in connection with the global sales of UNI-494; provided, however, that if we are required to make royalty payments to one or more third parties whose patent rights would be infringed by the exercise of the UNI-494 Rights, we may reduce such running royalty due to Sphaera by the amount of such third-party royalty rate.

We are also required to pay to Sphaera certain milestone payments, including, upon our initiation of a second clinical trial; $50,000 at the time the first patient in such trial is dosed; an additional $50,000 within 30 days of completion of such trial; and at the time the FDA accepts an NDA for UNI494, $1.65 million. In addition, we are responsible for the prosecution of patent rights, and any related costs and expenses for patent prosecution and maintenance.

We also have the right, but not the obligation, to defend the UNI-494 rights during the term of the Sphaera License Agreement; provided, however, that if we determine not to prosecute or maintain such rights in any country, we must provide ninety (90) days written notice to Sphaera. We may terminate the Sphaera License Agreement at any time by providing thirty (30) days' written notice to Sphaera. Additionally, in the event that either we or Sphaera breach any of our respective material obligations, the non-breaching party may, in its sole discretion, have the right to terminate the Sphaera License Agreement, provided that it give the breaching party written notice specifying the nature of the breach and amounts of running royalty payments due, if any. In such an occurrence, the termination notice is effective ninety (90) days from receipt of the notice if the breaching party has failed to cure the breach.

Competition

We operate in a highly competitive and regulated industry that is subject to rapid and frequent changes. We face significant competition from organizations that are pursuing products that would compete with the product candidates we are developing and the same or similar products that target the same conditions we intend to treat. Due to our limited resources, we may not be able to compete successfully against these organizations, which include many large, well-financed and experienced pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, as well as novel discoveries, product development technologies, and know-how.

Our commercial success also depends in part on our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to develop and maintain protection of our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and applications related to our technology, inventions, and improvements that are important to the development and implementation of our business.

We also rely on trademarks, trade secrets, know-how, continuing technological innovation, confidentiality agreements, and invention assignment agreements to develop and maintain our proprietary position. The confidentiality agreements are designed to protect our proprietary information and the invention assignment agreements are designed to grant us ownership of technologies that are developed for us by our employees, consultants, or other third parties. We seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in our agreements and security measures, either may be breached, and we may not have adequate remedies. In addition, our trade secrets may otherwise become known or independently discovered by competitors.

With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our 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 using and manufacturing the same.

Patent Portfolio

Oxylanthanum Carbonate

Our oxylanthanum carbonate patent portfolio includes one family of granted United States patents, with related applications pending, and an additional family of granted foreign patents, with related applications also pending. Granted and pending claims offer various forms of protection for oxylanthanum carbonate including claims to compositions of matter, pharmaceutical compositions, specific forms (such as polymorphs of lanthanum dioxycarbonate), methods of making the composition of matter, and methods for treating elevated levels of phosphate in the blood using oxylanthanum carbonate. These United States patents and applications, and their foreign equivalents, are described in more detail below.

Both the U.S. patent family and the foreign patent family containing claims to oxylanthanum carbonate and related compounds were filed in 2011. Exclusive of patent term extension, the U.S. patents from this family containing claims covering oxylanthanum carbonate has a statutory expiration date in 2032. Corresponding patents granted in Canada, Europe (validated in multiple European Patent Convention member states), Japan, China, Australia, and other countries have statutory expiration dates in 2032.

In some cases, granted United States patents claiming oxylanthanum carbonate have a longer statutory term than the corresponding foreign patents. We anticipate patent exclusivity until May 2036 with the patent term extension available for the ’240 patent. This results from the USPTO’s practice of granting patent term adjustments for prosecution delays originating at the USPTO. Such adjustments are generally not available under foreign patent laws. If oxylanthanum carbonate is approved for marketing in the United States, under the Hatch-Waxman Act we may be eligible for up to five years patent term extension for a granted United States patent containing claims covering oxylanthanum carbonate. Similar term extensions may be available in Europe, Japan, Australia, and certain other foreign jurisdictions. The amount of any such term extension, and the identity of the patent to which it would apply, are dependent upon several factors including the duration of the development program and the date of marketing approval.

The most relevant granted United States patents with claims covering oxylanthanum carbonate are listed below, along with their projected expiration dates exclusive of any patent term extension.

Patent Number	Title	Projected Expiration
8,961,917	Lanthanum carbonate hydroxide, lanthanum oxycarbonate and methods of their manufacture and use	October 26, 2032
10,350,240	Lanthanum carbonate hydroxide, lanthanum oxycarbonate and methods of their manufacture and use	November 12, 2032
11,406,663	Lanthanum carbonate hydroxide, lanthanum oxycarbonate and methods of their manufacture and use	May 12, 2031

UNI 494

We believe that we have a strong global intellectual property position, substantial know-how and trade secrets relating to UNI-494. As of October 28, 2020, we have one granted U.S. patent that is exclusively licensed to us from Sphaera Pharma Pte Ltd. In addition, we have four granted U.S. patents that we own. The first granted U.S. patent is directed to methods of making UNI-494, and it is expected to expire in 2032. The other granted U.S. patents are directed to methods of using UNI-494, and to other compositions of matter and are expected to expire in 2040.

Patent Number	Title	Projected Expiration
9,359,376	Substituted methylformyl reagents and method of using same to modify physicochemical and/or pharmacokinetic properties of compounds	July 11, 2032
12,036,211	Nicorandil derivatives	March 16, 2040
12,377,082	Nicorandil derivatives	March 16, 2040
12,396,989	Nicorandil derivatives	March 16, 2040

Government Regulations

Government authorities in the United States at the federal, state, and local level, including the FDA, the FTC and the DEA, extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, distribution, marketing and export and import of products such as those we plan to develop and market. For both the products under development and to be marketed, failure to comply with applicable regulatory requirements can, among other things, result in suspension of regulatory approval and possible civil and criminal sanctions. Regulations, enforcement positions, statutes and legal interpretations applicable to the pharmaceutical industry are constantly evolving and are not always clear. Significant changes in regulations, enforcement positions, statutes and legal interpretations could have a material adverse effect on our financial condition and results of our operations.

Additionally, future healthcare legislation or other legislative proposals at the federal and state levels could bring about major changes in the affected health care systems, including statutory restrictions on the means that can be employed by brand and generic pharmaceutical companies to settle Paragraph IV patent litigations. We cannot predict the outcome of such initiatives, but such initiatives, if passed, could result in significant costs to us in terms of costs of compliance and penalties associated with failure to comply.

Pharmaceutical Regulation in the United States

In the United States, the FDA regulates drugs under the Food, Drug and Cosmetic Act (FDCA) 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. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, Warning or Untitled Letters, product recalls, product seizures, total or partial suspension of production or distribution of product(s), injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug or a generic version of a previously approved drug, can be marketed in the United States.

The process required by the FDA before a new drug may be marketed in the United States generally involves:

- Completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's current good laboratory practice (GLP) regulations;
- Submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin in the United States;
- Approval by an institutional review board (IRB) at each clinical site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with the FDA good clinical practice (GCP) requirements and other clinical trial-related regulations to establish the safety and efficacy of the proposed drug product for each intended use;
- Satisfactory completion of a pre-approval inspection by FDA of the facility or facilities at which the product is manufactured to assess compliance with the FDA's cGMP regulations and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- Submission to the FDA of an NDA;
- Satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA review and approval of the NDA.

Preclinical Studies

When developing a branded product and bringing it to market, the first step in proceeding to clinical studies is preclinical testing. Preclinical tests are intended to provide a laboratory or animal study evaluation of the product to determine its chemistry, formulation, and stability. Toxicology studies are also performed to assess the potential safety of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. The results of these studies are submitted to the FDA as part of an IND application along with other information, including product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue concurrently with the IND application.

Clinical Trials

Once the IND has been approved by the FDA, the company may begin conducting clinical trials. Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it is initiated at that institution. Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on their www.clinicaltrials.gov website.

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

- **Phase 1**: The drug is initially introduced into healthy human subjects or patients with the target disease or condition, and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

- **Phase 2**: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance.

- **Phase 3**: The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2, and Phase 3 trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if it is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Marketing Approval

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include, among other things, the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. Under federal law, the submission of most NDAs is subject to a substantial application user fee, and the manufacturer or sponsor of an approved NDA is also subject to annual program fees. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit its substantive review. The FDA may request additional information rather than accept an NDA for filing. In some events, the NDA may be required to be resubmitted with additional information and it may be subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act, as amended, the FDA has agreed to certain performance goals for itself for the review of NDAs through a two-tiered classification system, Standard Review and Priority Review. Priority Review designation is given to drugs that are intended to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness over existing therapies. The FDA endeavors to review most applications subject to Standard Review within ten to twelve months whereas its goal is to complete most Priority Review applications within six to eight months, depending on whether the drug is a new molecular entity.

The FDA may refer applications for certain drug products which present difficult questions related to its safety or efficacy to an advisory committee for review, evaluation, and recommendation, and to seek advice as to whether the application should be approved and under what conditions. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the NDA unless it determines that the manufacturing process and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications, and the NDA contains data that provide substantial evidence that the drug is safe and effective for the labeled indication.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter to indicate that the review cycle for an application is complete and that the application is not ready for approval. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other elements to assure safe use, such as special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, the REMS must include a timetable to periodically assess the strategy. The requirement for a REMS can materially affect the potential market and profitability of a drug.

Sometimes, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or certain problems are identified following initial marketing. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms.

Further changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses similar procedures in reviewing NDA supplements as it does in reviewing the original NDAs.

Disclosure of Clinical Trial Information

Sponsors of certain clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information on www.clinical trials.gov. Information related to the product, subject population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss certain results of their clinical trials after their completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic reporting, product sampling and distribution, adverse event reporting, and advertising, marketing and promotion, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in a manner consistent with the provisions of the approved labeling. While physicians may choose to prescribe a drug for off-label uses, manufacturers may only promote it for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. There also are extensive DEA regulations applicable to controlled substances.

Adverse event reporting and submission of periodic reports is also required following FDA approval of an NDA. Additionally, the FDA may require post-marketing testing, known as Phase 4 testing, REMS, and/or surveillance to monitor the effects of an approved product. Alternatively, the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging and labeling procedures must continue to comply with cGMPs after its approval. Drug manufacturers and certain of their subcontractors are required to register their establishments and list their marketed products with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing or if previously unrecognized problems are subsequently discovered. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits outweigh its risks. In addition, regulatory authorities may take other enforcement action, including, among other things, Warning or Untitled Letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, refusal to approve pending applications or supplements to approved applications, civil penalties and criminal prosecution.

The Hatch-Waxman Amendments

505(b)(2) NDAs

The FDA is also authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference from the data owner. The applicant may rely upon the FDA's findings of safety and efficacy for an approved product that acts as the "listed drug." The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the listed drug. The FDA may then approve the new product candidate for all, or some, of the conditions of use for which the branded reference drug has been approved, or for a new condition of use sought by the 505(b)(2) applicant.

Abbreviated New Drug Applications

The Hatch-Waxman amendments to the FDCA established a statutory procedure for submission and FDA review and approval of abbreviated new drug applications (ANDAs) for generic versions of listed drugs. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient (API), drug product formulation, specifications, and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include clinical data to demonstrate safety and effectiveness. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. The bioequivalence studies for orally administered, systemically available drug products assess the rate and extent to which the API is absorbed into the bloodstream from the drug product and becomes available at the site of action. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the reference listed drug. For some drugs, other means of demonstrating bioequivalence may be required by the FDA, especially where rate or extent of absorption are difficult or impossible to measure. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the reference listed drug. A product is not eligible for ANDA approval if the FDA determines that it is not bioequivalent to the reference listed drug, if it is intended for a different use, or if it is not subject to, and requires, an approved Suitability Petition.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA (i) that there is no patent listed with the FDA as covering the relevant branded product, (ii) that any patent listed as covering the branded product has expired, (iii) that the patent listed as covering the branded product will expire prior to the marketing of the generic product, in which case the ANDA will not be finally approved by the FDA until the expiration of such patent or (iv) that any patent listed as covering the branded drug is invalid or will not be infringed by the manufacture, sale or use of the generic product for which the ANDA is submitted. A notice of the Paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the Paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the Paragraph IV certification, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug.

For example, for listed drugs that were considered new chemical entities at the time of approval, an ANDA or 505(b)(2) application referencing that drug may not be filed with the FDA until the expiration of five years after approval of that drug, unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. In addition, drugs approved for diseases for which the patient population is sufficiently small, or orphan indications, may be entitled to a seven-year data exclusivity period.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. 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 approved products for a particular indication. In addition, third-party payors may impose prior authorization or step edit requirements requiring patients to have tried other therapies prior to our products for coverage. Payors may also decline to include our products or product candidates on their formulary, which means that unless healthcare providers seek a medical exception for coverage, the payors will not pay for the product. In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product candidate could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

Dialysis-related drugs are included in the ESRD bundled prospective payment system (PPS) for renal dialysis services furnished to Medicare beneficiaries and are grouped into functional categories such as bone and mineral metabolism. Oral-only drugs were paid for outside of the bundle until their inclusion on January 1, 2025. Currently, CMS pays for phosphate binders through TDAPA (transitional drug add-on payment adjustment) which provides separate payment for hyperphosphatemia drugs for "no less than 2 years" based on the drug's Average Sales Price, or ASP, that is paid in addition to the base rate. The incremental cost associated with the addition of this class of drugs into the bundle will be assessed in the final year of the TDAPA and the base rate will be adjusted accordingly, and no further separate payment will be provided. We believe that oxylanthanum carbonate, if approved by FDA will be eligible for its own TDAPA for a period of 2 years, followed by an additional 3 years reduced payment of 65% of prior 12 months of OLC utilization.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Outside the United States, ensuring adequate coverage and payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require a clinical trial that compares the cost effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization. In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU member states may approve a specific price for a product or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Dialysis Organizations Protocols

Dialysis organizations have their own formularies that list primary or preferred therapeutic options based on contracting status with drug manufacturers. While a prescriber may make their own independent decision to prescribe what they determine most appropriate for a given patient, any non-formulary therapeutic options are only available through an exception process based on clinical need. Similar to how payor coverage may affect the sales of a product, formulary status within dialysis organizations may affect what products are prescribed within that specific organization. Therefore, if a product is not on a formulary, the prescribers within that organization may be less likely to prescribe that product or may have a difficult time prescribing that product, resulting in less sales. Further, one dialysis organization's determination to add a product to their formulary does not assure that other dialysis organizations will also add the product to theirs. There is always a risk a dialysis organization will not contract with a drug manufacturer for a specific product, resulting in that product not being on that organization's formulary. Additionally, dialysis organizations typically assess a product's efficacy before adding it to their formulary. Their process for assessing a product may differ among organizations and the timing of such assessment could delay adding such treatment to formulary, further affecting product sales.

Our ability to generate product revenue and achieve profitability depends on the overall success of oxylanthanum carbonate, UNI-494, and any current or future product candidates, including those that may be in-licensed or acquired, which depends on several factors, including:

- obtaining adequate or favorable pricing and reimbursement from private and governmental payors for UNI-494, and any other product or product candidate, including those that may be in-licensed or acquired;
- obtaining and maintaining market acceptance of oxylanthanum carbonate, UNI-494, and any other product candidate, including those that may be in-licensed or acquired;
- the size of any market in which oxylanthanum carbonate, UNI-494, and any other product or product candidate, including those that may be in-licensed or acquired, receives approval and obtaining adequate market share in those markets;
- the timing and scope of marketing approvals for oxylanthanum carbonate, UNI-494, and any other product candidate, if approved, including those that may be in-licensed or acquired;
- actual or perceived advantages or disadvantages of our products or product candidates as compared to alternative treatments, including their respective safety, tolerability and efficacy profiles, the potential convenience and ease of administration and cost;
- maintaining an acceptable safety and tolerability profile of our approved products, including the frequency and severity of any side effects;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies, based, in part, on their perception of our clinical trial data and/or the actual or perceived safety, tolerability and efficacy profile;

- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate supplies of products that are compliant with good manufacturing practices, or GMPs, to support the clinical development and the market demand for oxylanthanum carbonate, UNI-494, and any other product and product candidate, including those that may be in-licensed or acquired;

- current and future restrictions or limitations on our approved or future indications and patient populations or other adverse regulatory actions or in the event that the FDA requires Risk Evaluation and Mitigation Strategies, or REMS, or risk management plans that use restrictive risk minimization strategies;

- the effectiveness of our sales, marketing, manufacturing and distribution strategies and operations;

- competing effectively with any products for the same or similar indications as our products;

- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents and trade secrets; and

- the impact of the COVID-19 pandemic on the above factors, including the disproportionate impact of the COVID-19 pandemic on CKD patients, the adverse impact on the phosphate binder market in which we compete, and the limitation of our sales professionals to meet in person with healthcare professionals as the result of travel restrictions or limitations on access for non-patients.

Risks Related to Commercialization

Our business is substantially dependent on the commercial success of oxylanthanum carbonate, if approved. If we are unable to successfully commercialize oxylanthanum carbonate, our results or operations and financial condition will be materially harmed. Our ability to generate revenue depends on our ability to execute on our commercialization plans, and the size of the market for, and the level of market acceptance of, oxylanthanum carbonate and any other product or product candidate, including those that may be in-licensed or acquired. If the size of any market for which a product or product candidate is approved decreases or is smaller than we anticipate, our revenue and results of operations could be materially adversely affected. Market acceptance is also critical to our ability to generate significant product revenue. Any product may achieve only limited market acceptance or none at all. If oxylanthanum carbonate, or any of our product candidates that is approved, is not accepted by the market to the extent that we expect or market acceptance decreases, we may not be able to generate significant product revenue and our business would be materially harmed. Market acceptance of oxylanthanum carbonate or any other approved product depends on a number of factors, including:

- the availability of adequate coverage and reimbursement by and the availability of discounts, rebates, and price concessions from third party payors, pharmacy benefit managers, or PBMs, and governmental authorities;

- the safety and efficacy of the product, as demonstrated in clinical trials and in the post-marketing setting;

- the prevalence and complications of the disease treated by the product;

- the clinical indications for which the product is approved and the product label approved by regulatory authorities, including any warnings or limitations that may be required on the label as a consequence of potential safety risks associated with the product;

- the countries in which marketing approvals are obtained;
- the claims we and our collaborators are able to make regarding the safety and efficacy of the product;
- the success of our physician and patient communications and education programs;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the cost, safety and efficacy of the product in relation to alternative treatments;
- the timing of receipt of marketing approvals and product launch relative to competing products and potential generic entrants;
- relative convenience and ease of administration;
- the frequency and severity of adverse side effects;
- favorable or adverse publicity about our products or favorable or adverse publicity about competing products; and
- the effectiveness of our and our collaborators' sales, marketing, and distribution efforts.

In order to market oxylanthanum carbonate and any other approved product, we intend to invest in sales and marketing, which will require substantial effort and significant management and financial resources. Additionally, training a sales force to successfully sell and market a new commercial product is expensive and time-consuming and could delay any commercial launch of such product candidate. We may underestimate the size of the sales force required for a successful product launch and we may need to expand our sales force earlier and at a higher cost than we anticipated. We will devote significant effort, in particular, to recruiting individuals with experience in the sales and marketing of pharmaceutical products. Competition for personnel with these skills is significant and retaining qualified personnel with experience in our industry is difficult. As a result, we may not be able to retain our existing employees or hire new employees quickly enough to meet our needs. At the same time, we may face high turnover, requiring us to expend time and resources to source, train and integrate new employees. There are risks involved with building our own sales and marketing capabilities, including the following:

- potential inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- potential 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
- costs and expenses associated with maintaining our own sales and marketing organization.

If we are unable to build our own sales and marketing capabilities, we will not be successful in commercializing oxylanthanum carbonate, UNI-494, and any other product candidate that may be approved. Furthermore, if we are unable to maintain our arrangements with third parties with respect to sales and marketing, if we are unsuccessful in entering into additional arrangements with third parties to sell and market our products or we are unable to do so on terms that are favorable to us, or if such third parties are unable to carry out their obligations under such arrangements, it will be difficult to successfully commercialize our product and product candidates, including oxylanthanum carbonate, if approved.

Our, or our partners', failure to obtain or maintain adequate coverage, pricing and reimbursement for oxylanthanum carbonate, if approved, or any other future approved products, could have a material adverse effect on our or our collaboration partners' ability to sell such approved products profitably and otherwise have a material adverse impact on our business.

Market acceptance and sales of any approved products, including oxylanthanum carbonate and UNI-494, depends significantly on the availability of adequate coverage and reimbursement from third party payors and may be affected by existing and future healthcare reform measures. Governmental authorities, third party payors, and PBMs decide which drugs they will cover, as well as establish formularies or implement other mechanisms to manage utilization of products and determine reimbursement levels. We cannot be sure that coverage or adequate reimbursement will be available for oxylanthanum carbonate, UNI-494, or any of our potential future products. Even if we obtain coverage for an approved product, third party payors may not establish adequate reimbursement amounts, which may reduce the demand for our product and prompt us to reduce pricing for the product. If reimbursement is not available or is limited, we may not be able to commercialize certain of our products. Coverage and reimbursement by a governmental authority, third-party payor or PBM may depend upon a number of factors, including the determination that use of a product is:

- a covered benefit under the health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient; and
- cost effective.

Obtaining coverage and reimbursement approval for a product from a governmental authority, PBM or a third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. In the United States, there are multiple governmental authorities, PBMs and third-party payors with varying coverage and reimbursement levels for pharmaceutical products, and the timing of commencement of reimbursement by a governmental payor can be dependent on the assignment of codes via the Healthcare Common Procedural Coding System, which codes are assigned on a quarterly basis. Within Medicare, for oral drugs dispensed by pharmacies and also administered in facilities, coverage and reimbursement may vary depending on the setting. CMS, local Medicare administrative contractors, Medicare Part D plans and/or PBMs operating on behalf of Medicare Part D plans, may have some responsibility for determining the medical necessity of such drugs, and therefore coverage, for different patients. Different reimbursement methodologies may apply, and CMS may have some discretion in interpreting their application in certain settings. Additionally, we may be required to enter into contracts with third party payors and/or PBMs offering rebates or discounts on our products in order to obtain favorable formulary status and we may not be able to agree upon commercially reasonable terms with such third party payors or PBMs, or provide data sufficient to obtain favorable coverage and reimbursement for many reasons, including that we may be at a competitive disadvantage relative to companies with more extensive product lines. We currently believe it is likely that oxylanthanum carbonate, if approved, will be reimbursed using the Transitional Drug Add-on Payment Adjustment, or TDAPA, followed by inclusion in the bundled reimbursement model for Medicare beneficiaries. For those that obtain dialysis through commercial insurance during the 30-month coordination period or through Medicaid prior to Medicare becoming primary payer after 90 days, patients may access oxylanthanum carbonate through contracts we negotiate with third party payors for reimbursement of oxylanthanum carbonate, which would be subject to the risks and uncertainties described above. Additionally, applying for and obtaining reimbursement under the TDAPA may take an undetermined amount of time following approval, which will affect adoption, uptake, and product revenue for oxylanthanum carbonate during that time, and if there are updates to the TDAPA rule that decrease the basis for reimbursement or eligibility criteria during the transition period or if the TDAPA is eliminated, then our profitability may be adversely affected. Further, if oxylanthanum carbonate is approved in the United States and included in the fixed reimbursement model for a bundle of dialysis services, or the bundle, we would be required to enter into contracts to supply oxylanthanum carbonate to specific dialysis providers, instead of through distributors.

The dialysis market is unique and is dominated by two providers: DaVita and Fresenius, which account for a vast majority of the dialysis population in the United States. Similar to how payor coverage may affect the sales of a product, formulary status within dialysis organizations may affect what products are prescribed within that specific organization. Therefore, if a product is not on a formulary, the prescribers within that organization may be less likely to prescribe that product or may have a difficult time prescribing that product, resulting in less sales. Further, one dialysis organization's determination to add a product to their formulary does not assure that other dialysis organizations will also add the product to theirs. There is always a risk a dialysis organization will not contract with a drug manufacturer for a specific product, resulting in that product not being on that organization's formulary. If any dialysis organization does not add oxylanthanum carbonate, to the formulary, our business may be materially harmed. In addition, we may be unable to sell oxylanthanum carbonate to dialysis providers on a profitable basis if CMS significantly reduces the level of reimbursement for dialysis services and providers choose to use alternative therapies or look to re-negotiate their contracts with us. Adequate coverage and reimbursement of our products by government and private insurance plans are central to patient and provider acceptance of any products for which we receive marketing approval. Further, in many countries outside the United States, a drug must be approved for reimbursement before it can be marketed or sold in that country. In some cases, the prices that we intend to charge for our products are also subject to approval. Approval by the EMA or another regulatory authority does not ensure approval by reimbursement authorities in that jurisdiction, and approval by one reimbursement authority outside the United States does not ensure approval by any other reimbursement authorities. However, the failure to obtain reimbursement in one jurisdiction may negatively impact our ability to obtain reimbursement in another jurisdiction. We may not be able to obtain such reimbursement approvals on a timely basis, if at all, and favorable pricing in certain countries depends on a number of factors, some of which are outside of our control. In addition, if oxylanthanum carbonate is approved outside of the United States, we plan to rely on a partner to obtain approval by reimbursement authorities outside the United States. If we are unsuccessful or delayed in entering into an agreement with a new partner, the launch of oxylanthanum carbonate following approval outside the United States may be delayed, which could have an adverse effect on our results of operations.

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

The development and commercialization of new drugs is highly competitive and subject to rapid and significant technological change. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the development and commercialization of oxylanthanum carbonate, and any other product or product candidate, including those that may be in-licensed or acquired. oxylanthanum carbonate will compete in the hyperphosphatemia market in the United States with other FDA-approved phosphate binders such as Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate), both marketed by Sanofi, PhosLo® and Phoslyra® (calcium acetate), marketed by Fresenius Medical Care North America, Fosrenol® (lanthanum carbonate), marketed by Shire Pharmaceuticals Group plc, Velphoro® (sucroferric oxyhydroxide), marketed by Fresenius Medical Care North America, and Auryxia (ferric citrate), marketed by Akebia Therapeutics, Xphozah® (tenapanor), marketed by Ardelyx, as well as over-the-counter calcium carbonate products such as TUMS® and metal-based options such as aluminum, lanthanum and magnesium. Most of the phosphate binders listed above are now also available in generic forms. In addition, other agents are in development, including OPKO Health Inc.'s Alpharen™ Tablets (fermagate tablets) that may impact the market for oxylanthanum carbonate.

Smaller and other early-stage companies may also prove to be significant competitors.

As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or marketing approval, or discovering, developing and commercializing competitive products, before, or more effectively than, we do. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will suffer.

Healthcare Reform

In the United States, there have been a number of federal and state proposals during the last several years regarding the pricing of pharmaceutical products, government control and other changes to the healthcare system of the United States. It is uncertain what other legislative proposals may be adopted or what actions federal, state, or private payors may take in response to any healthcare reform proposals or legislation. We cannot predict the effect such reforms may have on our business, and no assurance can be given that any such reforms will not have a material adverse effect.

By way of example, in March 2010, the Affordable Care Act (the "ACA"), was signed into law, which, among other things, includes changes to the coverage and payment for drug products under government health care programs. The law includes measures that (i) significantly increase Medicaid rebates through both the expansion of the program and significant increases in rebates, (ii) substantially expand the Public Health System (340B) program to allow other entities to purchase prescription drugs at substantial discounts, (iii) extend the Medicaid rebate rate to a significant portion of Managed Medicaid enrollees, (iv) assess a rebate on Medicaid Part D spending in the coverage gap for branded and authorized generic prescription drugs, and (v) levy a significant excise tax on the industry to fund the healthcare reform.

In addition to the changes brought about by the ACA, other legislative changes have been proposed and adopted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year 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 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 drug products. Any proposed measures will require authorization through additional legislation to become effective. There can be no assurance that Congress or the Biden Administration intend to provide for such authorizations.

The Biden administration has also undertaken other actions – and may continue to do so – signaling a change in policy from the prior Trump administration. Such activities include Executive Order 13992, revoking several Trump administration orders that had certain deregulatory effects, and a letter to the United Nations retracting the United States' intent to withdraw from the World Health Organization.

The One Big Beautiful Bill Act, which was signed into law in July 2025, includes provisions that will impact the U.S. healthcare system in various ways, including by cuts to Medicaid and introducing new participant work and eligibility requirements for Medicaid coverage, which are expected to significantly change the administration and applicability of Medicaid coverage. In November 2025, CMS announced a voluntary initiative called the GENEROUS Model (GENErating cost Reductions for U.S. Medicaid Model) to introduce the option of most-favored-nation pricing to the Medicaid program, whereby a drug manufacturer may voluntarily offer supplemental rebates to participating state Medicaid programs for a manufacturer's covered outpatient drugs. Government agreements with pharmaceutical companies and other measures that use most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the U.S., or that increase generic and biosimilar drug entry sooner than expected, can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future. We cannot predict the full impact of the executive orders focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chain and manufacturing in the U.S. The impact of ongoing and future judicial challenges, as well as future legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the current administration, including the Department of Government Efficiency, on our company and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control prescription drug 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. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or product candidates or additional pricing pressures.

Other actions by the Trump administration and/or legislation passed by the new Congress could further impact the pharmaceutical and broader healthcare industries in ways that are difficult to predict but that could also materially impact our operations. We cannot predict what other healthcare reforms will ultimately be implemented at the federal or state level or the effect of any future legislation, executive action or regulation and, accordingly, face uncertainties that might result from additional reforms.

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

Healthcare Regulations

Pharmaceutical companies are subject to various federal and state laws that are intended to combat health care fraud and abuse and that govern certain of our business practices, especially our interactions with third-party payors, healthcare providers, patients, customers and potential customers through sales and marketing or research and development activities. These include anti-kickback laws, false claims laws, sunshine laws, privacy laws and FDA regulation of advertising and promotion of pharmaceutical products.

Anti-kickback laws, including the federal Anti-Kickback Statute, make it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referral of an individual for, or the purchase, order or recommendation of, any good or service reimbursable by, a federal health care program (including our products). The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing, or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, 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. Moreover, 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. The penalties for violating the federal Anti-Kickback Statute include administrative civil money penalties, imprisonment for up to five years, fines of up to $25,000 per violation and possible exclusion from federal healthcare programs such as Medicare and Medicaid.

The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit knowingly presenting, or causing to be presented, claims for payment to the federal government (including Medicare and Medicaid) that are false or fraudulent (and, under the Federal False Claims Act, a claim is deemed false or fraudulent if it is made pursuant to an illegal kickback). Manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Actions under the 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. Violations of the False Claims Act can result in significant monetary penalties, including fines ranging from $13,508 to $27,018 for each false claim, and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other improper sales and marketing practices. The government has obtained multi-million and multi-billion-dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. In addition, companies have been forced to implement extensive corrective action plans and have often become subject to consent decrees or corporate integrity agreements, severely restricting the manner in which they conduct their business. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The Federal Civil Monetary Penalties Law prohibits, among other things, the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance can result in civil money penalties ranging from $10,000 to $50,000 per violation and exclusion from the federal healthcare programs.

Federal criminal statutes 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. Like the federal Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Analogous state and foreign laws and regulations, including state anti-kickback and false claims laws, may apply to products and services reimbursed by non-governmental third-party payors, including commercial payors. Additionally, there are 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 that otherwise restrict payments that may be made to healthcare providers as well as state and foreign laws that require drug manufacturers to report marketing expenditures or pricing information and register sales representatives.

Sunshine laws, including the Federal Open Payments law enacted as part of the ACA, require pharmaceutical manufacturers to disclose payments and other transfers of value to physicians and certain other health care providers or professionals, and in the case of some state sunshine laws, restrict or prohibit certain such payments. Pharmaceutical manufacturers are required to submit reports to the government by the 90th day of each calendar year. Failure to submit the required information may result in civil monetary penalties of up to an aggregate of $100,000 per year, adjusted for inflation (or up to an aggregate of $1 million per year, adjusted for inflation for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations. Certain states and foreign governments require the tracking and reporting of gifts, compensation and other remuneration to physicians.

Privacy laws, such as the privacy regulations implemented under HIPAA, restrict covered entities from using or disclosing protected health information. Covered entities commonly include physicians, hospitals and health insurers from which we may seek to acquire data to aid in our research, development, sales and marketing activities. Although pharmaceutical manufacturers are not covered entities under HIPAA, our ability to acquire or use protected health information from covered entities may be affected by privacy laws. Specifically, HIPAA, as amended by HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security, and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain, or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

The FDA regulates the sale and marketing of prescription drug products and, among other things, prohibits pharmaceutical manufacturers from making false or misleading statements and from promoting products for unapproved uses. There has been an increase in government enforcement efforts at both the federal and state level. Numerous cases have been brought against pharmaceutical manufacturers under the Federal False Claims Act, alleging, among other things, that certain sales or marketing-related practices violate the Anti-Kickback Statute or the FDA's regulations, and many of these cases have resulted in settlement agreements under which the companies were required to change certain practices, pay substantial fines and operate under the supervision of a federally appointed monitor for a period of years. Due to the breadth of these laws and their implementing regulations and the absence of guidance in some cases, it is possible that our practices might be challenged by government authorities. Violations of fraud and abuse laws may be punishable by civil and criminal sanctions including fines, civil monetary penalties, as well as the possibility of exclusion of our products from payment by federal health care programs.

Government Price Reporting

Government regulations regarding reporting and payment obligations are complex, and we are continually evaluating the methods we use to calculate and report the amounts owed with respect to Medicaid and other government pricing programs. Our calculations are subject to review and challenge by various government agencies and authorities, and it is possible that any such review could result either in material changes to the method used for calculating the amounts owed to such agency or the amounts themselves. Because the process for making these calculations, and our judgments supporting these calculations, involve subjective decisions, these calculations are subject to audit. In the event that a government authority challenges or finds ambiguity with regard to our report of payments, such authority may impose civil and criminal sanctions, which could have a material adverse effect on our business. From time to time we conduct routine reviews of our government pricing calculations. These reviews may have an impact on government price reporting and rebate calculations used to comply with various government regulations regarding reporting and payment obligations.

Many governments and third-party payors reimburse the purchase of certain prescription drugs based on a drug's average wholesale price (AWP). In the past several years, state and federal government agencies have conducted ongoing investigations of manufacturers' reporting practices with respect to AWP, which they have suggested have led to excessive payments by state and federal government agencies for prescription drugs. We and numerous other pharmaceutical companies have been named as defendants in various state and federal court actions alleging improper or fraudulent practices related to the reporting of AWP.

Drug Pedigree Laws

State and federal governments have proposed or passed various drug pedigree laws which can require the tracking of all transactions involving prescription drugs from the manufacturer to the pharmacy (or other dispensing) level. Companies are required to maintain records documenting the chain of custody of prescription drug products beginning with the purchase of such products from the manufacturer. Compliance with these pedigree laws requires implementation of extensive tracking systems as well as heightened documentation and coordination with customers and manufacturers. While we fully intend to comply with these laws, there is uncertainty about future changes in legislation and government enforcement of these laws. Failure to comply could result in fines or penalties, as well as loss of business that could have a material adverse effect on our financial results.

Federal Regulation of Patent Litigation Settlements and Authorized Generic Arrangements

As part of the Medicare Prescription Drug Improvement and Modernization Act of 2003, companies are required to file with the U.S. Federal Trade Commission ("FTC") and the U.S. Department of Justice (the "DOJ") certain types of agreements entered into between brand and generic pharmaceutical companies related to the settlement of patent litigation or manufacture, marketing and sale of generic versions of branded drugs. This requirement could affect the manner in which generic drug manufacturers resolve intellectual property litigation and other disputes with brand pharmaceutical companies and could result generally in an increase in private-party litigation against pharmaceutical companies or additional investigations or proceedings by the FTC or other governmental authorities.

Other

The U.S. federal government, various states and localities have laws regulating the manufacture and distribution of pharmaceuticals, as well as regulations dealing with the substitution of generic drugs for branded drugs. Our operations are also subject to regulation, licensing requirements and inspection by the states and localities in which our operations are located or in which we conduct business.

Certain of our activities are also subject to FTC enforcement actions. The FTC also enforces a variety of antitrust and consumer protection laws designed to ensure that the nation's markets function competitively, are vigorous, efficient and free of undue restrictions. Federal, state, local and foreign laws of general applicability, such as laws regulating working conditions, also govern us.

In addition, we are subject to numerous and increasingly stringent federal, state and local environmental laws and regulations concerning, among other things, the generation, handling, storage, transportation, treatment and disposal of toxic and hazardous substances, the discharge of pollutants into the air and water and the cleanup of contamination. We are required to maintain and comply with environmental permits and controls for some of our operations, and these permits are subject to modification, renewal and revocation by the issuing authorities. Our environmental capital expenditures and costs for environmental compliance may increase in the future as a result of changes in environmental laws and regulations or increased manufacturing activities at any of our facilities. We could incur significant costs or liabilities as a result of any failure to comply with environmental laws, including fines, penalties, third-party claims and the costs of undertaking a clean-up at a current or former site or at a site to which our wastes were transported. In addition, we have grown in part by acquisition, and our diligence may not have identified environmental impacts from historical operations at sites we have acquired in the past or may acquire in the future.

Employees

As of March 30, 2026, we had 21 full-time employees and one part-time employee. We are not a party to any collective bargaining agreements. We believe that we maintain good relations with our employees.

Our Corporate History

We were incorporated as a Delaware corporation on August 18, 2016. Our principal executive offices are located at 1975 W El Camino Real, Ste 204, Mountain View, CA 94040, and our telephone number is (650) 351-4495.

Available Information

Our website address is *http://www.unicycive.com*. The contents of, or information accessible through, our website are not part of this Annual Report on Form 10-K, and our website address is included in this document as an inactive textual reference only. We make our filings with the SEC, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the SEC. The public may read and copy the materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is *www.sec.gov*. The information contained in the SEC's website is not intended to be a part of this filing.

ITEM 1A. RISK FACTORS.

An investment in our common stock involves a high degree of risk. You should carefully consider the following risk factors and the other information in this Annual Report on Form 10-K before investing in our common stock. Our business and results of operations could be seriously harmed by any of the following risks. The risks set out below are not the only risks we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. If any of the following events occur, our business, financial condition and results of operations could be materially adversely affected. In such case, the value and trading price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to our Financial Position and Need for Capital

We have generated no product revenue to date and our future profitability is uncertain.

We were incorporated in August 2016 and have a limited operating history, and our business is subject to all of the risks inherent in the establishment of a new business enterprise. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with the development and expansion of a new business enterprise. Since inception, we have incurred losses and expect to continue to operate at a net loss for at least the next several years as we continue our research and development efforts, conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. Our net loss for the years ended December 31, 2024 and 2025 was $36.7 million and $26.6million, and our accumulated deficit as of December 31, 2025 was $127.8 million. There can be no assurance that the product candidates currently under development or that may be under development by us in the future will be approved for sale in the U.S. or elsewhere. Furthermore, there can be no assurance that if such products are approved, they will be successfully commercialized, and the extent of our future losses and the timing of our profitability are highly uncertain. If we are unable to achieve profitability, we may be unable to continue our operations.

If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development and you will likely lose your entire investment.

We will need to continue to seek capital from time to time to continue development of our product candidates. As of December 31, 2024 and 2025, we had cash of $26.1 million and $29.2 million, respectively. On March 3, 2023, the entered into a securities purchase agreement with certain healthcare-focused institutional investors that will provide up to $130 million in gross proceeds to us through a private placement that included initial upfront funding of $30 million.

On March 13, 2024, we entered into a securities purchase agreement with certain accredited investors pursuant to which sold 50,000 shares of our Series B Convertible Preferred Stock at a purchase price of $1,000 per share with an initial conversion price of $1.00 per share, for an aggregate purchase price of $50.0million.

In addition, on November 13, 2024, we entered into a sales agreement, with Guggenheim Securities, LLC as amended by Amendment No. 1 thereto on November 14, 2025 (as amended, the "Sales Agreement") pursuant to which, we may offer and sell shares of our common stock having an aggregate offering price of up to $100 million, subject to certain limitations and in accordance with the terms of the Sales Agreement, from time to time through or to Guggenheim Securities, acting as sales agent or principal.

We believe that we will need to raise substantial additional capital in the future to fund our continuing operations and the development and commercialization of our current product candidates and future product candidates. Our business or operations may change in a manner that would consume available funds more rapidly than anticipated and substantial additional funding may be required to maintain operations, fund expansion, develop new or enhanced products, acquire complementary products, businesses or technologies or otherwise respond to competitive pressures and opportunities, such as a change in the regulatory environment. In addition, we may need to accelerate the growth of our sales capabilities and distribution beyond what is currently envisioned, and this would require additional capital. However, we may not be able to secure funding when we need it or on favorable terms. We may not be able to raise sufficient funds to commercialize our current and future product candidates we intend to develop.

If we cannot raise adequate funds to satisfy our capital requirements, we will have to delay, scale back or eliminate our research and development activities, clinical studies or future operations. We may also be required to obtain funds through arrangements with collaborators, which arrangements may require us to relinquish rights to certain technologies or products that we otherwise would not consider relinquishing, including rights to future product candidates or certain major geographic markets. This could result in sharing revenues which we might otherwise retain for ourselves. Any of these actions may harm our business, financial condition and results of operations.

The amount of capital we may need depends on many factors, including the progress, timing and scope of our product development programs; the progress, timing and scope of our pre-clinical studies and clinical trials; the time and cost necessary to obtain regulatory approvals; the time and cost necessary to further develop manufacturing processes and arrange for contract manufacturing; our ability to enter into and maintain collaborative, licensing and other commercial relationships; and our partners' commitment of time and resources to the development and commercialization of our products.

We may consider strategic alternatives in order to maximize stockholder value, including financings, strategic alliances, acquisitions or the possible sale of our business. We may not be able to identify or consummate any suitable strategic alternatives.

We may consider all strategic alternatives that may be available to us to maximize stockholder value, including financings, strategic alliances, acquisitions or the possible sale of our business. We currently have no agreements or commitments to engage in any specific strategic transactions, and our exploration of various strategic alternatives may not result in any specific action or transaction. To the extent that this engagement results in a transaction, our business objectives may change depending upon the nature of the transaction. There can be no assurance that we will enter into any transaction as a result of the engagement. Furthermore, if we determine to engage in a strategic transaction, we cannot predict the impact that such strategic transaction might have on our operations or stock price. We also cannot predict the impact on our stock price if we fail to enter into a transaction.

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

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or through the issuance of shares under management or other types of contracts, or upon the exercise or conversion of outstanding derivative securities, the ownership interests of our stockholders will be diluted, and the terms of such financings may include liquidation or other preferences, anti-dilution rights, conversion and exercise price adjustments and other provisions that adversely affect the rights of our stockholders, including rights, preferences and privileges that are senior to those of our holders of common stock in the event of a liquidation. In addition, debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends and may require us to grant security interests in our assets. If we raise additional funds through collaborations, strategi calliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, product 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 ordebt financings when needed, we may need to curtail or cease our operations.

You will experience dilution, subordination of stockholder rights, preferences, and privileges, and decrease in market price of our common stock as a result of our private placement financing in March 2023

On March 3, 2023, we signed a securities purchase agreement with certain healthcare-focused institutional investors pursuant to which we issued and sold 30,190 shares of Series A-1 Preferred Stock. Such Series A-1 Preferred Stock and the securities issuable upon conversion of the Series A-1 Preferred Stock are potentially dilutive instruments and the conversion of these securities upon Stockholder Approval in 2023 resulted in dilution to our existing stockholders: On July 11, 2023, the Series A-1 Preferred Stock was converted into 1,951,621 shares of common stock as well as 43,649 shares of Series A-2 Preferred Stock and Tranche A Warrants exercisable for Series A-3 Preferred Stock convertible into 4,785,243 shares of common stock, Tranche B Warrants exercisable for SeriesA-4 Preferred Stock convertible into 4,350,229 shares of common stock and Tranche C warrants exercisable for Series A-5 Preferred Stock convertible into 6,960,362 shares of commons stock. In March 2024, the 43,649 shares of Series A-2 Preferred Stock was exchanged for 21,388.01 shares of Series A-2 Prime Preferred Stock convertible into 4,364,900 shares of common stock. As of the date of this report there were outstanding 2,265 shares of Series A-2 Prime Preferred Stock convertible into 462,245 shares of common stock. In addition, there were outstanding Tranche A Warrants exercisable for Series A-3 Preferred Stock convertible into 4,508,252 shares of common stock, Tranche B Warrants exercisable for SeriesA-4 Preferred Stock convertible into 4,350,229 shares of common stock and Tranche C warrants exercisable for Series A-5 Preferred Stock convertible into 6,960,362 shares of commons stock.

As a result of the agreements, these stockholders, acting together, may have 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. In addition, these stockholders, acting together, may have the ability to control the management and affairs of our company.

Our cash could be adversely impacted if a financial institution with which we have deposits or other accounts fails.

Our cash and cash equivalents we use to satisfy our working capital and operating expense needs are held in accounts at various financial institutions. The balance held in deposit accounts often exceeds the Federal Deposit Insurance Corporation ("FDIC") deposit insurance limit or similar government deposit insurance schemes. Our cash and cash equivalents could be adversely impacted, including the loss of uninsured deposits and other uninsured financial assets, if one or more of the financial institutions in which we hold our cash or cash equivalents fails or is subject to other adverse conditions in the financial or credit markets. Any loss of our cash or cash equivalents or any delay in our access thereto could, among other risks, adversely impact our ability to pay our operating expenses, result in breaches of our contractual obligations, or result in violations of federal or state wage and hour laws if we are unable to pay our employees on a timely basis.

Risks Related to Our Business

The marketing approval process of the FDA is lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our current product candidates and future product candidates we intend to develop, our business will be substantially harmed.

The product candidates we intend to develop have not gained marketing approval in the U.S., and we cannot guarantee that we will ever have marketable products. Our business is substantially dependent on our ability to complete the development of, obtain marketing approval for, and successfully commercialize our current and future product candidates in a timely manner. We cannot commercialize our product candidates in the United States without first obtaining approval from the FDA to market each product candidate. Our product candidates could face substantial delays or even fail to receive marketing approval for many reasons, including among others:

- The FDA may decide that additional CMC, nonclinical and clinical studies would be needed for the approval of oxylanthanum carbonate;
- the FDA may disagree with the design, implementation, or interpretation of data of our CMC, preclinical, or clinical studies;
- the FDA could determine that we cannot rely on specific regulatory approval pathway, e.g., Section 505(b)(2), for our current or future product candidates; and
- the FDA may determine that we have identified the wrong reference listed drug or drugs or that approval of our regulatory application for any of our product candidates is blocked by patent or non-patent exclusivity of the reference listed drug or drugs.

In addition, the process of seeking regulatory clearance or approval to market the product candidates we intend to develop is expensive and time-consuming and, notwithstanding the effort and expense incurred, clearance or approval is never guaranteed. If we are not successful in obtaining timely clearance or approval of our product candidates from the FDA, we may never be able to generate anticipated revenue and may be forced to cease operations. The NDA process is costly, lengthy and uncertain. Any NDA application filed by us will have to be supported by extensive data, including, but not limited to, technical, pre-clinical, clinical, manufacturing, and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the product for its intended use.

Obtaining clearances or approvals from the FDA and from the regulatory agencies in other countries is an expensive and time-consuming process and is uncertain as to outcome. The FDA and other agencies could ask us to supplement our submissions, collect new CMC or non-clinical data, conduct additional clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain an NDA approval or pre-market approvals in other countries, the approval could be revoked, or other restrictions imposed if post-market data demonstrate safety issues or lack of effectiveness. In response to our initial NDA submission, the FDA issued a CRL notifying us that a third-party manufacturing vendor of its main contract development and manufacturing organization (CDMO) was cited for deficiencies following a cGMP inspection. We resubmitted an NDA in December 2025 and the FDA set a PDUFA target action date of June 29, 2026. If the third party fails inspection again or if the NDA is rejected again, we will need to make another NDA submission and our target PDUFA target action date will be extended by another 6-12 months. We cannot predict with certainty how, or when, the FDA or other regulatory agencies will act. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be adversely affected, and our ability to grow domestically and internationally may be limited. Additionally, even if cleared or approved, our products may not be approved for the specific indications that are most necessary or desirable for successful commercialization or profitability.

We may encounter substantial delays in completing our clinical studies which in turn will require additional costs, or we may fail to demonstrate adequate safety and efficacy to the satisfaction of applicable regulatory authorities.

It is impossible to predict if or when our current or future product candidates will prove safe or effective in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. Clinical testing is expensive, time-consuming and uncertain as to outcome. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in reaching, or failing to reach, a consensus with regulatory agencies on study design;
- delays in reaching, or failing to reach, agreement on acceptable terms with a sufficient number of prospective contract research organizations("CROs") and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in recruiting a sufficient number of suitable patients to participate in our clinical studies;
- imposition of a clinical hold by regulatory agencies, after an inspection of our clinical study operations or study sites;
- failure by our CROs, other third parties or us to adhere to clinical study, regulatory or legal requirements including cGMP requirements;
- failure to perform in accordance with the FDA's good clinical practices ("GCPs") or applicable regulatory guidelines in other countries;
- delays in the testing, validation, manufacturing and delivery of sufficient quantities of our product candidates to the clinical sites;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- clinical study sites or patients dropping out of a study;

- delay or failure to address any patient safety concerns that arise during the course of a trial;
- unanticipated costs or increases in costs of clinical trials of our product candidates;
- occurrence of serious adverse events associated with the product candidates that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the Institutional Review Board ("IRB") or Ethics Commission ("EC") of the institutions in which such trials are being conducted, by an independent Safety Review Board ("SRB") for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial 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.

Any inability to successfully complete pre-clinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions.

Clinical study delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidates' development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, 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 regulatory approval of our product candidates.

The outcome of pre-clinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Further, pre-clinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval. If the results of our clinical studies are inconclusive or if there are safety concerns or adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates, if approved at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be required to change the way the product is administered;
- be required to perform additional clinical studies to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw their approval of a product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be sued; or
- experience damage to our reputation.

Additionally, our product candidates could potentially cause other adverse events that have not yet been predicted. The inclusion of ill patients in our clinical studies 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 achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products.

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

Our product candidates and the activities associated with its development and commercialization, including its design, testing, manufacture, release, safety, efficacy, regulatory filings, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, is subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. For example, in order to commence clinical trials of our product candidates in the United States, we must file an IND and obtain FDA agreement to proceed. The FDA may place our development program on clinical hold and require further pre-clinical testing prior to allowing our clinical trials to proceed.

We must obtain marketing approval in each jurisdiction in which we market our products. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not submitted a marketing application or received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and supporting information to the various regulatory authorities for each indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process, testing and release and inspection of manufacturing facilities and personnel by the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidate involved. We cannot assure you that we will ever obtain any marketing approvals in any jurisdiction. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional pre-clinical or other studies, changes in the manufacturing process or facilities or clinical trials. Moreover, approval by the FDA or an equivalent foreign authority, including the HSA, does not ensure approval by regulatory authorities in any other countries or jurisdictions, but a failure to obtain marketing approval in one jurisdiction may adversely impact the likelihood of approval in other jurisdictions. In addition, varying interpretations of the data obtained from pre-clinical testing, manufacturing and product testing and clinical trials could delay, limit or prevent marketing approval of a product candidate. Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Modifications to our products may require new NDA approvals.

Once a particular product receives FDA approval or clearance, expanded uses or uses in new indications of our products may require additional human clinical trials and new regulatory approvals or clearances, including additional IND and NDA submissions and premarket approvals before we can begin clinical development, and/or prior to marketing and sales. If the FDA requires new clearances or approvals for a particular use or indication, we may be required to conduct additional clinical studies, which would require additional expenditures and harm our operating results. If the products are already being used for these new indications, we may also be subject to significant enforcement actions. Conducting clinical trials and obtaining clearances and approvals can be a time-consuming process, and delays in obtaining required future clearances or approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Additional delays to the completion of clinical studies may result from modifications being made to the protocol during the clinical trial, if such modifications are warranted and/or required by the occurrences in the given trial.

Each modification to the protocol during a clinical trial has to be submitted to the FDA. This could result in the delay or halt of a clinical trial while the modification is evaluated. In addition, depending on the quantity and nature of the changes made, the FDA could take the position that the data generated by the clinical trial are not poolable because the same protocol was not used throughout the trial. This might require the enrollment of additional subjects, which could result in the extension of the clinical trial and the FDA delaying clearance or approval of a product. Any such delay could have a material adverse effect on our business and results of operations.

There can be no assurance that the data generated from our clinical trials using modified protocols will be acceptable to the FDA or other regulatory authorities.

There can be no assurance that the data generated using modified protocols will be acceptable to the FDA or other regulatory authorities or that if future modifications during the trial are necessary, that any such modifications will be acceptable to the FDA or other regulatory authorities. If the FDA or other regulatory authorities believe that prior approval is required for a particular modification, they can delay or halt a clinical trial while they evaluate additional information regarding the change.

Serious injury or death resulting from a failure of our product candidates during current or future clinical trials could also result in the FDA or other regulatory authority delaying our clinical trials or denying or delaying clearance or approval of a product.

Even though an adverse event may not be the result of the failure of our product candidate, the FDA or other regulatory authority could delay or halt a clinical trial for an indefinite period of time while an adverse event is reviewed, and likely would do so in the event of multiple such events.

Any delay or termination of our current or future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from the FDA or other regulatory authorities, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or adverse events during the trials, may cause an increase in costs and delays in the filing of any product submissions with the FDA or other regulatory authorities, delay the approval and commercialization of our products or result in the failure of the clinical trial, which could adversely affect our business, operating results and prospects.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.

Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators; support staff; and the proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.

The future results of our current or future clinical trials may not support our product candidates claims or may result in the discovery of unexpected adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product candidates claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses. If the FDA concludes that the clinical trials for any product for which we might seek clearance, has failed to demonstrate safety and effectiveness, we would not receive FDA clearance to market that product in the United States for the indications sought.

In addition, such an outcome could cause us to abandon a product candidate and might delay development of others. Any delay or termination of our clinical trials will delay the filing of any product submissions with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of our product candidate's profile.

Adverse events involving our products may lead the FDA or other regulatory authorities to delay or deny clearance for our products or result in product recalls that could harm our reputation, business and financial results.

Once a product receives FDA clearance or approval, the agency has the authority to require the recall of commercialized products in the event of adverse side effects, material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is a reasonable probability that the product would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of adverse side effects, impurities or other product contamination, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within ten working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA and/or other regulatory agencies could take enforcement action for failing to report the recalls when they were conducted.

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

If our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community for us to achieve commercial success. If our product candidates do not achieve an adequate level of acceptance, we may not generate sufficient product revenue to become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative therapies;
- the size of the markets in the countries in which approvals are obtained;
- terms, limitations, or warnings contained in any labeling approved by the FDA or other regulatory authority;
- our ability to offer any approved products for sale at competitive prices;

- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies or dosing regimens;
- the willingness of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the success of competing products and the marketing efforts of our competitors;
- sufficient third-party payor coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

Even if we are able to commercialize our product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage, and reimbursement for new drugs vary widely from country to country. In the United States, new 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 drug 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 pharmaceutical pricing remains subject to continuing governmental control even after initial marketing approval is granted. As a result, we might obtain marketing approval for a drug in a particular country but then be subject to price regulations that delay its commercial launch, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to commercialize and generate revenue from our product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize our current and any future product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health programs, private health insurers, integrated delivery networks and other third-party payors. Third-party payors decide which medications they will pay for and establish reimbursement levels. A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payment for particular medications. Increasingly, third-party payors are requiring that drug companies provide predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement may not be sufficient for commercial success. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and adequate reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that any product 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 drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Coverage and reimbursement rates may vary according to the use of the drug and the medical circumstances under which it is used may be based on reimbursement levels already set for lower cost products or procedures or may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Commercial third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded programs and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our approved products and our overall financial condition.

Any product candidate for which we obtain marketing approval could be subject to marketing restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of promotional materials and safety and other post-marketing information and reports, registration and listing requirements, current Good Manufacturing Practice ("cGMP") requirements for product facilities, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and related recordkeeping. 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 may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the product's FDA approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not comply with these restrictions, we may be subject to enforcement actions.

In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes and facilities or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on such products, manufacturers or manufacturing processes or facilities;
- restrictions on the labeling, marketing, distribution or use of a product;
- requirements to conduct post-approval clinical trials, other studies or other post-approval commitments;
- warning or untitled letters;
- withdrawal or recall of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

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.

We have limited financial resources. As a result, we may forego or delay pursuit of opportunities with future product candidates or for other indications that later prove to have greater commercial potential than opportunities we pursue. 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 markets for a particular product candidate or opportunity, we may relinquish valuable rights to that product candidate or opportunity 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 or opportunity.

Our reliance on third parties heightens the risks faced by our business.

We rely on suppliers, vendors and partners for certain key aspects of our business, including support for information technology systems and certain human resource functions. We do not control these partners, but we depend on them in ways that may be significant to us. For example, our third-party manufacturing vendor of its main contract development and manufacturing organization (CDMO) was cited for deficiencies following a cGMP inspection resulting in the FDA issuing us a CRL for our initial NDA submission which resulted in us having to resubmit an NDA causing delay in our target action PFUDA date of 12-months. If these parties fail to meet our expectations or fulfill their obligations to us, we may fail to receive the expected benefits. In addition, if any of these third parties fails to comply with applicable laws and regulations in the course of its performance of services for us, there is a risk that we may be held responsible for such violations as well. This risk is particularly serious in emerging markets, where corruption is often prevalent and where many of the third parties on which we rely do not have internal compliance resources comparable to our own. Any such failures by third parties, in emerging markets or elsewhere, could adversely affect our business, reputation, financial condition or results of operations.

We intend to rely on third parties to conduct our clinical trials and to conduct some aspects of our research and pre-clinical testing and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We expect to rely on third parties, such as CROs (contract research organizations), CMOs (contract manufacturers) of clinical supplies, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and to conduct some aspects of our research and pre-clinical testing. These third parties may terminate their engagements with us at any time. If these third parties do not successfully carry out their duties, meet expected deadlines or conduct our studies 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 product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If we are required to enter into alternative arrangements, it could delay our product development activities.

Our reliance on 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 and other international regulatory authorities require us to comply with GCP standards 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. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, available at www.clinicaltrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Upon commercialization of our products, we may be dependent on third parties to market, distribute and sell our products.

Our ability to receive revenues may be dependent upon the sales and marketing efforts of any future co-marketing partners and third-party distributors. At this time, we have not entered into an agreement with any commercialization partner and only plan to do so prior to commercialization. If we fail to reach an agreement with any commercialization partner, or upon reaching such an agreement that partner fails to sell a large volume of our products, it may have a negative impact on our business, financial condition and results of operations.

We have no experience manufacturing product candidates on a clinical or commercial scale and will be dependent on third parties for the manufacture of our product candidates. If we experience problems with any of these third parties or their subcontractors or vendors, they could delay clinical development or marketing approval of our product candidates or our ability to sell any approved products.

We do not have any manufacturing facilities. We expect to rely on third-party manufacturers for the manufacture of our product candidates for clinical trials and for commercial supply of any product candidate for which we obtain marketing approval.

We may be unable to establish agreements with third-party manufacturers for clinical or commercial supply on terms favorable to us, or at all. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party, including the inability to supply sufficient quantities or to meet quality standards or timelines; and
- the possible termination or non-renewal 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 U.S. cGMPs or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, or their subcontractors, to comply with cGMPs or other applicable regulations, even if such failures do not relate specifically to our product candidates or approved products, could result in sanctions being imposed on us or the manufacturers, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of our product candidates and harm our business and results of operations. For example, our third-party manufacturing vendor of its main contract development and manufacturing organization (CDMO) was cited for deficiencies following a cGMP inspection resulting in the FDA issuing us a CRL for our initial NDA submission which resulted in us having to resubmit an NDA causing delay in our target action PFUDA date of 12-months.

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

Any performance failure on the part of our manufacturers, including a failure that may not relate specifically to our product candidates or approved products, could delay clinical development or marketing approval or adversely impact our ability to generate commercial sales. If our contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer.

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

Furthermore, we expect to rely on third parties to release, label, store and distribute drug supplies for our clinical trials. Any performance failure on the part of these third parties, including a failure that may not relate specifically to our product candidates, could delay or otherwise adversely impact clinical development or marketing approval of our product candidates or commercialization of our drug, producing losses and depriving us of potential revenue. Our supplier Shilpa Medicare Ltd was reviewed by the FDA in March 2025.

Moreover, our manufacturers and suppliers may experience difficulties related to their overall businesses and financial stability, which could result in delays or interruptions of supply of our product candidates.

We may have conflicts with our partners that could delay or prevent the development or commercialization of our current and future product candidates.

We may have conflicts with our partners, such as conflicts concerning the interpretation of pre-clinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our current and future product candidates, and in turn prevent us from generating revenues:

- unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due to us under a collaboration;
- uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations;
- unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials;
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities;
- initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or
- attempts by either party to terminate the agreement.

Our products will face significant competition, and if they are unable to compete successfully, our business will suffer.

Our current product candidates and future candidates face, and will continue to face, intense competition from large pharmaceutical companies, as well as academic and research institutions. We compete in an industry that is characterized by: (i) rapid technological change, (ii) evolving industry standards, (iii)emerging competition and (iv) new product introductions. Our competitors have existing products and technologies that will compete with our products and technologies and may develop and commercialize additional products and technologies that will compete with our products and technologies. Because several competing companies and institutions have greater financial resources than us, they may be able to: (i) provide broader services and product lines, (ii) make greater investments in research and development and (iii) carry on larger research and development initiatives than us. Our competitors also have greater development capabilities than we do and have substantially greater experience in undertaking pre-clinical and clinical testing of products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. They also have greater name recognition and better access to customers than us.

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

We face an inherent risk of product liability exposure related to the testing of our current product candidates or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our product. If we cannot successfully defend ourselves against claims that our product candidates or product caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire clinical trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

Prior to engaging in future clinical trials, we intend to obtain product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks; however, we may be unable to obtain such coverage at a reasonable cost, if at all. If we are able to obtain product liability insurance, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise, and such insurance may not be adequate to cover all liabilities that we may incur. Furthermore, we intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may fail to strengthen our competitive position and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies, and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Security threats to our information technology infrastructure and/or our physical buildings could expose us to liability and damage our reputation and business.

It is essential to our business strategy that our technology and network infrastructure and our physical buildings remain secure and are perceived by our customers and corporate partners to be secure. Despite security measures, however, any network infrastructure may be vulnerable to cyber-attacks by hackers and other security threats. We may face cyber-attacks that attempt to penetrate our network security, sabotage, or otherwise disable our research, products and services, misappropriate our or our customers' and partners' proprietary information, which may include personally identifiable information, or cause interruptions of our internal systems and services. Despite security measures, we also cannot guarantee security of our physical buildings. Physical building penetration or any cyber-attacks could negatively affect our reputation, damage our network infrastructure and our ability to deploy our products and services, harm our relationship with customers and partners that are affected, and expose us to financial liability.

Additionally, there are a number of state, federal and international laws protecting the privacy and security of health information and personal data. For example, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers, healthcare clearinghouses, and health insurance plans, or, collectively, covered entities, and also grants individuals rights with respect to their health information. HIPAA also imposes compliance obligations and corresponding penalties for non-compliance on individuals and entities that provide services to healthcare providers and other covered entities. As part of the American Recovery and Reinvestment Act of 2009 ("ARRA") the privacy and security provisions of HIPAA were amended. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. As amended by ARRA and subsequently by the final omnibus rule adopted in 2013, HIPAA also imposes notification requirements on covered entities in the event that certain health information has been inappropriately accessed or disclosed, notification requirements to individuals, federal regulators, and in some cases, notification to local and national media. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with encryption or other standards developed by the U.S. Department of Health and Human Services. Most states have laws requiring notification of affected individuals and/or state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms, to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

We will need to grow the size of our organization in the future, and we may experience difficulties in managing this growth.

As of December 31, 2025, we had 21 full-time employees. We will need to grow the size of our organization in order to support our continued development and potential commercialization of our product candidates. As our development and commercialization plans and strategies continue to develop, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources may increase. Our management, personnel, and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;

- improving our managerial, development, operational, information technology, and finance systems; and
- expanding our facilities.

If our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively, as well as our ability to develop a sales and marketing force when appropriate. To that end, we must be able to manage our development efforts and pre-clinical studies and clinical trials effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. The failure to accomplish any of these tasks could prevent us from successfully growing our company.

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

We are highly dependent upon our personnel, including Dr. Shalabh Gupta, our Chief Executive Officer and members of our board of directors. The loss of Dr. Gupta's services could impede the achievement of our research, development and commercialization objectives. We have not obtained, do not own, nor are we the beneficiary of, key-person life insurance. Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results. Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the pharmaceutical field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business.

Inadequate funding for the FDA, the U.S. Securities and Exchange Commission ("SEC") and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

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 the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

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 beginning on December 22, 2018, the U.S. government has shutdown several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government 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. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Intellectual Property

Our UNI 494 product candidate is subject to an exclusive license agreement. If we fail to meet our obligations and the license is terminated, we may not be able to continue to develop our product candidates.

On October 1, 2017, we entered into an exclusive license agreement (the "Sphaera License Agreement") with Sphaera Pharma Pte. Ltd., a Singaporean pharmaceutical corporation ("Sphaera"). Pursuant to the Sphaera License Agreement, we acquired an exclusive royalty-bearing worldwide license to develop, make, have made, use, practice, research, distribute, lease, sell, offer for sale, license, import or otherwise dispose of certain rights owned or controlled by Sphaera and/or any of its affiliates, related to UNI 494 (the "UNI 494 Rights"). We also acquired a non-exclusive license to certain know-how and technology related to the UNI 494 Rights. In the event that either party to the Sphaera License Agreement breaches any of its material obligations thereunder, the non-breaching party, at its sole option and discretion, will have the right to terminate the Sphaera License Agreement, provided that it must give the breaching party written notice specifying the nature of the breach, amounts of certain royalties and other payments then due, if any. The non-breaching Party's termination notice is effective 90 days from receipt of the written notice if the breaching party has failed to cure such breach within the 90-day period. If the Sphaera License Agreement were to be terminated by Sphaera due to our material breach, we would lose a significant asset and may no longer be able to develop our product candidates, which would have a material adverse effect on our operations.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current product candidates and future product candidates, the processes used to manufacture them and the methods for using them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the U.S. or in foreign jurisdictions outside of the U.S. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently license or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our product candidates or technology could be adversely affected.

Others may file patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition, reexamination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are similar to our product candidates, but that are not covered by the claims of our licensed patents;
- any patents that we obtain from licensing or otherwise may not provide us with any competitive advantages;
- any granted patents that we rely upon may be held invalid or unenforceable as a result of legal challenges by third parties; and
- the patents of others may have an adverse effect on our business.

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

We may be required to enter into intellectual property license agreements that are important to our business. These license agreements may impose various diligence, milestone payment, royalty and other obligations on us. For example, we may enter into exclusive license agreements with various universities and research institutions, we may be required to use commercially reasonable efforts to engage in various development and commercialization activities with respect to licensed products and may need to satisfy specified milestone and royalty payment obligations. If we fail to comply with any obligations under our agreements with any of these licensors, we may be subject to termination of the license agreement in whole or in part; increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize products covered by the license agreement will be impaired.

In addition, disputes may arise regarding intellectual property subject to a license 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;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third-party expresses interest in an area under a license that we are not pursuing, under the terms of certain of our license agreements, we may be required to sublicense rights in that area to a third party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize our product candidates.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our product candidates, or manufacture or use of our product candidates, will not infringe third-party patents. Furthermore, a third party may claim that we are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. Some of these third parties may be better capitalized and have more resources than us. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable way around the patent and may need to halt commercialization of our product candidates. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. In addition, we may be obligated to indemnify our licensors and collaborators against certain intellectual property infringement claims brought by third parties, which could require us to expend additional resources. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform.

If we are sued for patent infringement, we would need to demonstrate that our product candidates or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and diversion of management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than us or the third parties from whom we license intellectual property because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and product could be significantly diminished.

We also rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its transparency initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

We may be subject to claims that our employees or consultants have wrongfully used or disclosed alleged trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees or consultants have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail to defend any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Our intellectual property may not be sufficient to protect our product candidates from competition, which may negatively affect our business as well as limit our partnership or acquisition appeal.

We may be subject to competition despite the existence of intellectual property we license or may in the future own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition. Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our product candidates or future product candidates.

We may elect to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we either own or license from a third party. If we do not prevail in enforcing our intellectual property rights in this type of litigation, we may be subject to:

- paying monetary damages related to the legal expenses of the third party;
- facing additional competition that may have a significant adverse effect on our product pricing, market share, business operations, financial condition, and the commercial viability of our product; and
- restructuring our company or delaying or terminating select business opportunities, including, but not limited to, research and development, clinical trial, and commercialization activities, due to a potential deterioration of our financial condition or market competitiveness.

A third party may also challenge the validity, enforceability or scope of the intellectual property rights that we license or own and the result of these challenges may narrow the scope or claims of or invalidate patents that are integral to our product candidates in the future. There can be no assurance that we will be able to successfully defend patents we own or license in an action against third parties due to the unpredictability of litigation and the high costs associated with intellectual property litigation, amongst other factors.

Intellectual property rights and enforcement may be less extensive in jurisdictions outside of the U.S. Therefore, we may not be able to protect our intellectual property and third parties may be able to market competitive products that may use some or all of our intellectual property.

Changes to patent law, including the Leahy-Smith America Invests Act of 2011 and the Patent Reform Act of 2009 and other future article of legislation, may substantially change the regulations and procedures surrounding patent applications, issuance of patents and prosecution of patents. We can give no assurances that the patents of our licensor can be defended or will protect us against future intellectual property challenges, particularly as they pertain to changes in patent law and future patent law interpretations.

Risks Related to Healthcare Compliance and Other Regulations

If we fail to comply with healthcare regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

We could be subject to healthcare fraud and abuse laws and patient privacy laws of both the federal government and the states in which we conduct our business. The laws include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;

- HIPAA which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the FDCA which among other things, strictly regulates drug manufacturing and product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. 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 management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Our, or our partners', failure to obtain or maintain adequate coverage, pricing and reimbursement for oxylanthanum carbonate (OLC), if approved, or any other future approved products, could have a material adverse effect on our or our collaboration partners' ability to sell such approved products profitably and otherwise have a material adverse impact on our business.

Market acceptance and sales of any approved products, including OLC, if approved, depends significantly on the availability of adequate coverage and reimbursement from third party payors and may be affected by existing and future healthcare reform measures. Governmental authorities, third party payors, and PBMs decide which drugs they will cover, as well as establish formularies or implement other mechanisms to manage utilization of products and determine reimbursement levels. We cannot be sure that coverage or adequate reimbursement will be available for OLC, if approved, or any of our potential future products. Even if we obtain coverage for an approved product, third party payors may not establish adequate reimbursement amounts, which may reduce the demand for our product and prompt us to have to reduce pricing for the product. If reimbursement is not available or is limited, we may not be able to successfully commercialize certain of our products. Coverage and reimbursement by a governmental authority, third-party payor or PBMs may depend upon a number of factors, including the determination that use of a product is:

- a covered benefit under the health plan;

- safe, effective and medically necessary;

- appropriate for the specific patient; and

- cost effective.

Obtaining coverage and reimbursement approval for a product from a governmental authority, PBM or a third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. In the U.S., there are multiple governmental authorities, PBMs and third-party payors with varying coverage and reimbursement levels for pharmaceutical products, and the timing of commencement of reimbursement by a governmental payor can be dependent on the assignment of codes via the Healthcare Common Procedural Coding System, which codes are assigned on a quarterly basis. Within Medicare, for oral drugs dispensed by pharmacies and also administered in facilities, coverage and reimbursement may vary depending on the setting. CMS, local Medicare administrative contractors, Medicare Part D plans and/or PBMs operating on behalf of Medicare Part D plans, may have some responsibility for determining the medical necessity of such drugs, and therefore coverage, for different patients. Different reimbursement methodologies may apply, and CMS may have some discretion in interpreting their application in certain settings.

In the current reimbursement environment, oral phosphate lowering therapies like OLC are covered by Medicare under Part D for the treatment of patients with hyperphosphatemia. In January 2011, CMS implemented the ESRD PPS, a prospective payment system for dialysis treatment. Under the ESRD PPS, CMS generally makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all items and services routinely required for dialysis treatments furnished to Medicare beneficiaries in Medicare-certified ESRD facilities or at their home. The inclusion of oral medications without injectable or intravenous equivalents such as OLC in the bundled payment was initially delayed by CMS until January 1, 2014, and through several subsequent legislative actions has been delayed until January 1, 2025. Given the potential approval timeline for OLC in mid-2025, our drug would be launched into this bundled setting.

Absent further legislation or regulation on this matter, beginning in January 2025, oral ESRD-related drugs without injectable or intravenous equivalents, including phosphate lowering medications, will be included in the ESRD bundle and separate Medicare payment for these drugs will no longer be available, as is the case today under Medicare Part D. ESRD facilities may nonetheless receive a TDAPA for new renal dialysis drugs and biological products that meet certain criteria for a minimum of two years. The TDAPA will provide separate payment based on the drug's Average Sales Price, or ASP, that will be in addition to the base rate in order to facilitate the adoption of innovative therapies. There can be no assurances that CMS will not again delay the inclusion of these oral ESRD-related drugs in the bundled payment. Moreover, in the post-TDAPA period, CMS currently expects to increase the single bundled payment base rate paid to the dialysis facility for each dialysis treatment to reflect that oral only phosphate lowering drugs will be reimbursed as part of the single bundled payment for Medicare patients. There can be no assurances that any increase in the single bundled payment base rate will be sufficient to adequately reimburse the dialysis facilities for OLC at a price that is profitable for us.

Medicaid reimbursement of drugs varies by state. Private third-party payor reimbursement policies also vary and may or may not be consistent with Medicare reimbursement methodologies. Manufacturers of outpatient prescription drugs may be required to provide discounts or rebates under government healthcare programs or to certain third-party payors in order to obtain coverage of such products.

Additionally, we may be required to enter into contracts with third party payors and/or PBMs offering rebates or discounts on our products in order to obtain favorable formulary status and we may not be able to agree upon commercially reasonable terms with such third party payors or PBMs, or provide data sufficient to obtain favorable coverage and reimbursement for many reasons, including that we may be at a competitive disadvantage relative to companies with more extensive product lines. In addition, third party payors, PBMs and other entities that purchase our products may impose restrictions on our ability to raise prices for our products over time without incurring additional costs.

We currently believe it is likely that OLC, if approved, will be reimbursed using the Transitional Drug Add-on Payment Adjustment, or TDAPA, followed by inclusion in the bundled reimbursement model for Medicare beneficiaries, but reimbursement under TDAPA it is subject to review and approval by CMS. For those that obtain dialysis through commercial insurance during the 30-month coordination period or through Medicaid prior to Medicare becoming primary payor after 90 days, patients may access OLC through contracts we negotiate with third party payors for reimbursement of OLC, which would be subject to the risks and uncertainties described above. Additionally, applying for and obtaining reimbursement under the TDAPA is expected to take six months following filing acceptance, which will affect adoption, uptake and product revenue for OLC during that time, and if there are updates to the TDAPA rule that decrease the basis for reimbursement or eligibility criteria during the transition period or if the TDAPA is eliminated, then our profitability may be adversely affected.

Further, if OLC is approved in the U.S., we expect it to be included in the fixed reimbursement model for a bundle of dialysis services, or the bundle, which may require us to enter into contracts to supply OLC to specific dialysis providers, instead of through distributors, which we believe could be challenging. The dialysis market is unique and is dominated by two providers: DaVita and Fresenius Medical Care, which account for a vast majority of the dialysis population in the U.S.

Similar to how payor coverage may affect the sales of a product, formulary status within dialysis organizations may affect what products are prescribed within that specific organization. Therefore, if a product is not on a formulary, the prescribers within that organization may be less likely to prescribe that product or may have a difficult time prescribing that product, resulting in less sales. Further, one dialysis organization's determination to add a product to their formulary does not assure that other dialysis organizations will also add the product to theirs. There is always a risk a dialysis organization will not contract with a drug manufacturer for a specific product, resulting in that product not being on that organization's formulary. If any dialysis organization does not add OLC, if approved, to the formulary, our business may be materially harmed.

In addition, we may be unable to sell OLC, if approved, to dialysis providers on a profitable basis if CMS significantly reduces the level of reimbursement for dialysis services and providers choose to use alternative therapies or look to re-negotiate their contracts with us. Our profitability may also be affected if our costs of production increase faster than increases in reimbursement levels. Adequate coverage and reimbursement of our products by government and private insurance plans are central to patient and provider acceptance of any products for which we receive marketing approval. Existing competitive products may enter into sole source agreements with dialysis providers that impact the ability for new product innovations and new competitors may face price pressure based on existing contracts with dialysis providers.

Further, in many countries outside the U.S., a drug must be approved for reimbursement before it can be marketed or sold in that country. In some cases, the prices that we intend to charge for our products are also subject to approval. Approval by the EMA or another regulatory authority does not ensure approval by reimbursement authorities in that jurisdiction, and approval by one reimbursement authority outside the U.S. does not ensure approval by any other reimbursement authorities. However, the failure to obtain reimbursement in one jurisdiction may negatively impact our ability to obtain reimbursement in another jurisdiction. In addition, we plan to rely on a partner to obtain approval by reimbursement authorities outside the U.S. Our partners may not be able to obtain such reimbursement approvals on a timely basis, if at all, and favorable pricing in certain countries depends on a number of factors, some of which are outside of our partners' control.

Healthcare Reform in the United States.

In the United States, there have been, and continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect the future results of pharmaceutical manufactures' operations. In particular, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. For example, the Affordable Care Act ("ACA"), which was originally enacted in March 2010 and subsequently amended, includes measures to significantly change the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of greatest importance to the pharmaceutical and biotechnology industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- implementation of the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act";
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, that are inhaled, infused, instilled, implanted or injected;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; and

Some of the provisions of the ACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the ACA. The former Trump administration issued certain executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 included 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." Congress may consider other legislation to repeal or replace elements of the ACA.

Many of the details regarding the implementation of the ACA are yet to be determined, and at this time, the full effect that the ACA would have on a pharmaceutical manufacturer remains unclear. In particular, there is uncertainty surrounding the applicability of the biosimilars provisions under the ACA. This uncertainty is heightened by President Biden's January 28, 2021 Executive Order on Strengthening Medicaid and the Affordable Care Act, which indicates that the Biden administration may significantly modify the ACA and potentially revoke any changes implemented by the Trump administration.

The FDA has issued several guidance documents, but no implementing regulations, on biosimilars. A number of biosimilar applications have been approved over the past few years. The regulations that are ultimately promulgated and their implementation are likely to have considerable impact on the way pharmaceutical manufacturers conduct their business and may require changes to current strategies. A biosimilar is a biological product that is highly similar to an approved drug notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the approved drug in terms of the safety, purity, and potency of the product.

Individual states 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 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 a pharmaceutical manufacturer's 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 ultimate demand for certain products or put pressure on product pricing, which could negatively affect a pharmaceutical manufacturer's business, results of operations, financial condition and prospects.

The One Big Beautiful Bill Act, which was signed into law in July 2025, includes provisions that will impact the U.S. healthcare system in various ways, including by cuts to Medicaid and introducing new participant work and eligibility requirements for Medicaid coverage, which are expected to significantly change the administration and applicability of Medicaid coverage. In November 2025, CMS announced a voluntary initiative called the GENEROUS Model (GENErating cost Reductions for U.S. Medicaid Model) to introduce the option of most-favored-nation pricing to the Medicaid program, whereby a drug manufacturer may voluntarily offer supplemental rebates to participating state Medicaid programs for a manufacturer's covered outpatient drugs. Government agreements with pharmaceutical companies and other measures that use most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the U.S., or that increase generic and biosimilar drug entry sooner than expected, can have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover R&D costs, ability to attract potential investors and potential buyers in the future. We cannot predict the full impact of the executive orders focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chain and manufacturing in the U.S. The impact of ongoing and future judicial challenges, as well as future legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the current administration, including the Department of Government Efficiency, on our company and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control prescription drug 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. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or product candidates or additional pricing pressures.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, the Trump administration, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. For example, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

While no one can predict the full outcome of any such legislation, it may result in decreased reimbursement for drugs and biologics, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm a pharmaceutical manufacturer's ability to generate revenue. Increases in importation or re-importation of pharmaceutical products from foreign countries into the United States could put competitive pressure on a pharmaceutical manufacturer's ability to profitably price products, which, in turn, could adversely affect business, results of operations, financial condition and prospects. A pharmaceutical manufacturer might elect not to seek approval for or market products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue generated from product sales. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and integrity oversight and reporting obligations.

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 U.S. Foreign Corrupt Practices Act of 1977, as amended, 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 for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase 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.

Risks Related to Owning our Common Stock

The price of our common stock may fluctuate substantially.

You should consider an investment in our common stock to be risky, and you should invest in our common stock only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, are:

- sale of our common stock by our stockholders, executives, and directors;
- volatility and limitations in trading volumes of our shares of common stock;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities;
- possible delays in the expected recognition of revenue due to lengthy and sometimes unpredictable sales timelines;
- the timing and success of introductions of new products by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- network outages or security breaches;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our product candidates or any future clinical trials we may conduct;

- changes in the development status of our product candidates;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned pre-clinical and clinical trials;
- any delay in our submission for studies or product approvals or adverse regulatory decisions, including failure to receive regulatory approval for our product candidates;
- unanticipated safety concerns related to the use of our product candidates;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales of large blocks of common stock by our stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- competition from existing technologies and products or new technologies and products that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendations and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual property, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

We do not intend to pay cash dividends on our shares of common stock so any returns will be limited to the value of our shares, except we have agreed to pay cash dividends in the event oxylanthanum carbonate is approved by the FDA and commercial sales is commenced.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future, except that in March 2023,we agreed with certain investors to modify our dividend policy to state that we intend to pay dividends to all stockholders on a quarterly basis in an amount of which the aggregate of all quarterly dividends shall equal at least seventy-five percent (75%) of our annual net cash flow from operations following the approval of oxylanthanum carbonate by the FDA if obtained, and the commencement of commercial sales.

Market and economic conditions may negatively impact our business, financial condition and share price.

Concerns over medical epidemics, energy costs, geopolitical issues, the U.S. mortgage market and a deteriorating real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns (including the current downturn related to the COVID-19 pandemic), volatile business environments and continued unstable or unpredictable economic and market conditions. If these conditions continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and share price and could require us to delay or abandon development or commercialization plans.

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume may decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock after the closing of this offering, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

If we fail to comply with the continued listing requirements of the Nasdaq Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our Common Stock is currently listed on the Nasdaq Capital Market and the continued listing of our Common Stock on the Nasdaq Capital Market is contingent on our continued compliance with a number of listing requirements. If we are unable to comply with the continued listing requirements of the Nasdaq Capital Market, our Common Stock would be delisted from the Nasdaq Capital Market, which would limit investors' ability to effect transactions in our Common Stock and subject us to additional trading restrictions. In order to maintain our listing, we must maintain certain share prices, financial and share distribution targets, including maintaining a minimum amount of stockholders' equity and a minimum number of public stockholders, as well as satisfy other listing requirements of the Nasdaq Capital Market. In addition to these objective standards, Nasdaq Capital Market may delist the securities of any issuer for other reasons involving the judgment of Nasdaq Capital Market.

There is no assurance that we will be able to maintain compliance with the Nasdaq Capital Market continued listing standards and/or continue our listing on the Nasdaq Capital Market in the future.

If the Nasdaq Capital Market delists our Common Stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect the Common Stock would qualify to be quoted on an over-the-counter market. If this were to occur, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- substantially impair our ability to raise additional funds;
- the loss of institutional investor interest and a decreased ability to issue additional securities or obtain additional financing in the future;
- a determination that our Common Stock is a "penny stock," which will require brokers trading in our Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- potential breaches of representations or covenants of our agreements pursuant to which we made representations or covenants relating to our compliance with applicable listing requirements, which, regardless of merit, could result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations.

Because certain of our stockholders control a significant number of shares of our common stock, they may have effective control over actions requiring stockholder approval.

As of December 31, 2025, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 39% of our outstanding shares of common stock. As a result, these stockholders, acting together, have the ability to control the outcome of matters submitted to ours stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring, or preventing a change in corporate control;
- 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.

We are an "emerging growth company" and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the 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 stockholder approval of any golden parachute payments not previously approved. In addition, pursuant to Section 107 of the JOBS Act, as an "emerging growth company" we intend to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (the "Securities Act"), for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We cannot predict if investors will find our common stock less attractive because we may 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. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.2 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and results in a decline in the market price of our common stock.

Our amended and restated certificate of incorporation ("Amended and Restated Certificate of Incorporation") and our amended and restated bylaws (the "Amended and Restated Bylaws"), and Delaware law may have anti-takeover effects that could discourage, delay or prevent a change in control, which may cause our stock price to decline.

Our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 10 million shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters),preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and Delaware law, as applicable, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval;
- place limitations on the removal of directors;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Financial reporting obligations of being a public company in the U.S. are expensive and time-consuming, and our management will be required to devote substantial time to compliance matters.

As a publicly traded company we will incur significant additional legal, accounting and other expenses that we did not incur as a privately held company. The obligations of being a public company in the U.S. require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company." In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

Our Amended and Restated Certificate of Incorporation, provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between the Company and its stockholders, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with the Company or its directors, officers or employees.

Our Amended and Restated Certificate of Incorporation, provides that unless we consent in writing to the selection of an alternative forum, the State of Delaware is the sole and exclusive forum for: (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of our Company to us or our stockholders, (iii) any action asserting a claim against us, our directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law (the "DGCL") or our Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws or (iv) any action asserting a claim against us, our directors, officers, employees or agents governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, or other federal securities laws or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our Amended and Restated Certificate of Incorporation contains a federal forum provision which provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock are deemed to have notice of and consented to this provision. The Supreme Court of Delaware has held that this type of exclusive federal forum provision is enforceable. There may be uncertainty, however, as to whether courts of other jurisdictions would enforce this provision, if applicable.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find our choice of forum provisions contained in our Amended and Restated Certificate of Incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition.

Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the preparation of our financial statements for the years ended December 31, 2024 and 2025, we concluded that our internal control over financial reporting was effective. However, we may identify material weaknesses in our internal control over financial reporting in future years, and investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our core business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We believe cybersecurity is critical to achieving our drug development advancements. As a biotechnology company, we face a multitude of cybersecurity threats that range from attacks common to most industries, such as ransomware and denial-of service. Our suppliers, subcontractors, and business partners face similar cybersecurity threats, and a cybersecurity incident impacting us or any of these entities could materially adversely affect our operations, performance, and results of operations. These cybersecurity threats and related risks make it imperative that we expend resources on cybersecurity.

Our Board of Directors oversees management's processes for identifying and mitigating risks, including cybersecurity risks, to help align our risk exposure with our strategic objectives. Senior leadership regularly briefs the Board of Directors on our cybersecurity and information security posture and the Board of Directors is apprised of cybersecurity incidents deemed to have a moderate or higher business impact, even if immaterial to us. The full Board retains oversight of cybersecurity because of its importance. In the event of an incident, we intend to follow our detailed incident response playbook, which outlines the steps to be followed from incident detection to mitigation, recovery, and notification, including notifying functional areas (e.g., legal), as well as senior leadership and the Board, as appropriate. Our Cybersecurity consultant has extensive information technology and program management experience. We have implemented a governance structure and processes to assess, identify, manage, and report cybersecurity risks

As a biotechnology company, we must comply with extensive regulations, including requirements imposed by the Food and Drug Administration related to adequately safeguarding patient information and reporting cybersecurity incidents to the SEC. We work with our cybersecurity consultant on assessing cybersecurity risk and on policies and practices aimed at mitigating these risks. We believe we are positioned to meet the requirements of the SEC. In addition to following SEC guidance and implementing pre-existing third party frameworks, we have developed our own practices and frameworks, which we believe enhance our ability to identify and manage cybersecurity risks. Third parties also play a role in our cybersecurity. We engage third-party services to conduct evaluations of our security controls, whether through penetration testing, independent audits, or consulting on best practices to address new challenges. Assessing, identifying, and managing cybersecurity related risks are factored into our overall business approach.

We rely heavily on our vendors and suppliers to deliver our products and services, and a cybersecurity incident at a supplier, subcontractor or business partner could materially adversely impact us. We require that our subcontractors report cybersecurity incidents to us so that we can assess the impact of the incident onus. Notwithstanding the extensive approach we take to cybersecurity, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. The costs related to cybersecurity threats or disruptions may not be fully insured. See “Risk Factors” for a discussion of cybersecurity risks.

ITEM 2. PROPERTIES

Our principal address is 4300 El Camino Real, Suite 210, Los Altos, CA 94022. We believe our facilities are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate alternative space would be readily available on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

On August 15, 2025, a putative shareholder class action complaint captioned *Elkhodari v. Unicycive Therapeutics, Inc., et al.*, Case No. 3:25-cv-06923-JD (the “Securities Class Action”), was filed in the U.S. District Court for the Northern District of California (“Northern District of California”), naming the Company and certain current officers and/or directors of the Company as defendants. The lawsuit generally alleges that the Company made material misrepresentations and/or omissions of material fact relating to the Company’s manufacturing of oxylanthanum carbonate (“OLC”) and the approval prospects of its New Drug Application for OLC for the treatment of hyperphosphatemia in CKD patients on dialysis in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder. The putative class action is brought on behalf of persons or entities who purchased or otherwise acquired the Company’s securities between March 29, 2024, and June 27, 2025, inclusive, and seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorneys’ fees. On January 27, 2026, Plaintiff filed an amended complaint. On March 13, 2026, defendants filed their motion to dismiss the amended complaint. . At this early stage of the proceedings, the Company is unable to make any prediction regarding the outcome of the Securities Class Action.

On October 30 and November 7, 2025, two purported stockholders of the Company filed derivative complaints in the Northern District of California against certain of the Company’s current officers and directors (collectively, the “Derivative Actions”). The Company is named as a nominal defendant. The complaints are based on the same alleged misconduct as in the Securities Class Action. The complaints assert state law claims on behalf of the Company against the individual defendants for breach of fiduciary duty, unjust enrichment, gross mismanagement, and waste of corporate assets, and federal claims under Section 14(a) of the Exchange Act. On November 20, 2025, the Court issued an order relating the Derivative Actions to the Securities Class Action. The Derivative Actions seek unspecified damages on behalf of the Company, corporate governance reforms, disgorgement and restitution, and an award of costs and expenses, including attorneys’ fees.

On March 12, 2026, a purported stockholder made a demand on the Company’s Board of Directors to commence a civil action against certain of the Company’s current and former officers and directors for breaching their fiduciary duties based on the same alleged misconduct as alleged in the above-mentioned Securities Class Action and Derivative Actions (the “Demand”).

At this early stage of the proceedings, the Company is unable to make any prediction regarding the outcome of the Securities Class Action, the Derivative Actions, or the Demand.

In addition, from time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

On July 13, 2021, our common stock began trading on The Nasdaq Capital Market under the symbol "UNCY." Prior to that time, there was no public market for our common stock.

Stockholders

As of March 30, 2026, there were 98 stockholders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future, except that in March 2023,we agreed with certain investors to modify our dividend policy to state that we intend to pay dividends to all stockholders on a quarterly basis in an amount of which the aggregate of all quarterly dividends shall equal at least seventy-five percent (75%) of our annual net cash flow from operations following the approval of oxylanthanum carbonate by the FDA if obtained, and the commencement of commercial sales.

Recent Sales of Unregistered Securities

None.

Issuers Purchases of Equity Securities

None.

ITEM 6. [RESERVED]

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

You should read the following discussion and analysis of our financial condition and plan of operations together with our accompanying financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report on Form 10-K. All amounts in this report are in U.S. dollars, unless otherwise noted.

Overview

We are a clinical-stage biotechnology company focused on identifying, developing, and commercializing innovative therapies to address significant unmet medical needs, with an initial focus on kidney disease. Founded in 2016, we were established to create a streamlined and efficient drug development platform capable of accelerating the advancement of promising therapies from discovery to commercialization. Currently, our two programs are focused on kidney disease, an area we believe we have the potential to offer medical benefit. Our initial focus is on developing drugs and getting them approved in the U.S., and then to partner with global biopharmaceutical companies in the rest of the world. As we grow the company and build our team, we intend to focus on identifying medical conditions within and outside of kidney disease. Our business model is to license technologies and drugs in order to pursue development, regulatory approval, and commercialization of those products in global markets. Many biotechnology companies utilize similar strategies of in-licensing and then developing and commercializing drugs. We believe, however, that our management team's broad network, expertise in the biopharmaceutical industry, and successful track record gives us an advantage in identifying and bringing these assets into our company.

Our current development programs are focused on two novel therapies: oxylanthanum carbonate, a next-generation phosphate binder for the treatment of hyperphosphatemia in chronic kidney disease patients on dialysis, and UNI-494, a novel drug candidate in development for the treatment of acute kidney injury. oxylanthanum carbonate and UNI-494 were initially developed by and licensed to us from Spectrum Pharmaceuticals ("Spectrum") and Sphaera Pharma, respectively. Spectrum conducted a Phase 1 clinical trial with oxylanthanum carbonate in 2012, prior to the grant of our license in 2018. Sphaera conceived and performed initial characterization of various potential pro-drug linkers, including the initial patent application. As discussed herein, after completing IND enabling preclinical studies, we have completed a Phase I clinical study in healthy volunteers with UNI-494 in 2024.

Chronic kidney disease (CKD) is the gradual loss of kidney (renal) function that can get worse over time leading to lasting damage and possibly Stage 5 or end-stage renal disease (ESRD). CKD affects nearly 36 million Americans; approximately 550,000 of them have end stage renal disease and require dialysis. Hyperphosphatemia is common in people with CKD and has been directly linked to increased morbidity and mortality for people on dialysis. For an estimated 75% of people in the U.S. on dialysis, hyperphosphatemia remains uncontrolled due to challenges with the six currently available phosphate binders, namely insufficient potency, pill burden and unpalatable formulations. To address this significant and growing challenge, Unicycive is developing oxylanthanum carbonate, which leverages proprietary nanoparticle technology to address the shortcomings of current therapies by delivering higher potency that enables fewer and smaller pills — all in a formulation that is more acceptable for patients because it is swallowed, not chewed. With OLC, if approved, people on dialysis and their physicians may have a better option to control hyperphosphatemia.

AKI is a sudden episode of kidney failure or kidney damage (within the first 90 days of injury). After 90 days, the patient is considered to have progressed into CKD. AKI affects more than 2 million U.S. patients and costs the healthcare system in excess of $9 billion per year. More than 300,000 patients per year in the U.S. die due to AKI. Currently there are no FDA approved medicines to treat DGF and/or AKI. Treatment options for AKI include continuous renal replacement therapy, renal transplant, and dialysis. In most cases the damage to the kidney is irreversible, and the patient needs to have a renal transplant or be on dialysis for life. Therefore, there is a high unmet medical need. If approved, UNI-494 has the potential to be a first-in-class drug for the treatment of AKI.

Our business model is to license technologies and drugs in order to pursue development, regulatory approval, and commercialization of those products in global markets. Many biotechnology companies utilize similar strategies of in-licensing and then developing and commercializing drugs. We believe, however, that our management team's broad network, expertise in the biopharmaceutical industry, and successful track record gives us an advantage in identifying and bringing these assets into our company.

Since our formation we have devoted substantially all of our resources to developing our product candidates. We have incurred significant operating losses to date. Our net losses were $36.7 million and $26.6 million for the years ended December 31, 2024 and 2025 respectively. As of December 31, 2025, we had an accumulated deficit of $127.8 million. We expect that our operating expenses will increase significantly as we advance our product candidates through pre-clinical and clinical development, seek regulatory approval, and prepare for and, if approved, proceed to commercialization; acquire, discover, validate, and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel.

We have funded our operations primarily from the sale and issuance of common stock, convertible promissory notes and from a loan, including cash and deferred salary from our Chief Executive Officer and principal stockholder.

Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of our current product candidates and future product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into agreements to raise capital as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our current product candidates and future product candidates.

We plan to continue to use third-party service providers, including contract manufacturing organizations, to carry out our pre-clinical and clinical development and to manufacture and supply the materials to be used during the development and commercialization of our product candidates.

Recent Developments

On October 28, 2025,we announced an update from our meeting with the U.S. Food and Drug Administration (FDA) and timing of the resubmission of our New Drug Application (NDA) for oxylanthanum carbonate (OLC) following receipt of a CRL on June 30, 2025. The Type A FDA meeting was held to discuss the resolution of the single deficiency identified in the CRL related to the compliance status of a third-party manufacturing vendor. No other concerns have been identified to us, including pre-clinical, clinical, or safety data submitted as part of the NDA. Following receipt of the official meeting minutes from the Type A meeting and engaging in discussions with our third-party manufacturing vendor, we resubmitted our NDA to the FDA in December 2025. In January 2026, the FDA accepted the resubmission of the NDA for OLC, deeming the resubmission to be a Class II complete response which has a six-month review period from the date of resubmission, and set a PDUFA target action date of June 29, 2026

Subsequent to December 31, 2025, pursuant to a sales agreement dated November 13, 2024 between the Company and Guggenheim Securities, LLC, as amended by Amendment No. 1 thereto dated November 14, 2025, the Company sold 3,123,537 shares of common stock at an average price of $6.51 per share, resulting in net proceeds to the Company of approximately $19.6 million.

Components of Results of Operations

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of our product candidates. These expenses include fees paid to third parties to conduct certain research and development activities on our behalf, consulting costs, costs for laboratory supplies, product acquisition and license costs, certain payroll and personnel-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expenses for our research and product development employees and allocated overheads, including information technology costs and utilities and expenses for the issuance of shares pursuant to the anti-dilution clause in the purchase of in process research and development technology. We expense both internal and external research and development expenses as are incurred.

We do not allocate our costs by product candidate, as a significant amount of research and development expenses include internal costs, such as payroll and other personnel expenses, laboratory supplies and allocated overhead, and external costs, such as fees paid to third parties to conduct research and development activities on our behalf, are not tracked by product candidate.

We expect our research and development expenses to increase substantially for at least the next few years, as we seek to initiate additional clinical trials for our product candidates, complete our clinical programs, pursue regulatory approval of our product candidates and prepare for the possible commercialization of such product candidates. Predicting the timing or cost to complete our clinical programs or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our product candidates will receive regulatory approval with any certainty.

General and Administrative Expenses

General and administrative expenses consist principally of payroll and personnel expenses, including salaries and bonuses, benefits and stock-based compensation expenses, professional fees for legal (including patent costs), consulting, accounting and tax services, including information technology costs and utilities, and *other general corporate overhead expenses.*

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, expanded infrastructure and higher consulting, legal and accounting services costs associated with complying with the applicable stock exchange and the SEC requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

Other Expenses

Other expenses consist of the change in fair value of our warrant liability, interest income and interest expense.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2025 (in thousands)

	Years Ended December 31,			%
	2024	**2025**	**Change**	**Change**
Operating expenses:				
Research and development	$ 20,014	$ 9,121	$ (10,893)	(54)%
General and administrative	12,103	20,396	8,293	69%
Total operating expenses	32,117	29,517	(2,600)	(8)%
Loss from operations	(32,117)	(29,517)	2,600	(8)%
Other income (expenses):				
Interest income	1,261	1,012	(249)	(20)%
Interest expense	(71)	(71)	-	0%
Change in fair value of warrant liability	(5,802)	2,021	7,823	(135)%
Total other income (expenses)	(4,612)	2,962	7,574	(164)%
Net loss	$ (36,729)	$ (26,555)	10,174	(28)%

Research and Development Expenses

Research and development expenses decreased by approximately $10.9 million, or 54%, from approximately $20.0 million for the year ended December 31, 2024 to approximately $9.1 million for the year ended December 31, 2025. This decrease was primarily driven by a reduction in drug development costs of $8.0 million and a decline in clinical costs of $3.4 million. These decreases were partially offset by increased costs, including $0.2 million in consulting and professional services and $0.2 million in labor. Additionally, stock-based compensation rose by $0.1 million.

General and Administrative Expenses

General and administrative expenses increased by $8.3 million, or 69%, from approximately $12.1 million for the year ended December 31, 2024 to approximately $20.4 million for the year ended December 31, 2025. This increase was primarily driven by a $2.4 million rise in marketing expenses associated with the commercial launch, $3.5 million in higher consulting and professional service costs, and $1.8 million in labor and related expenses. Additionally, rent, travel, supplies, and other costs increased by $0.5 million, while stock-based compensation grew by $0.1 million.

Other Income (Expenses)

Other income (expenses) improved by $7.6 million, or 164%, from an expense of $4.6 million for the year ended December 31, 2024, to income of $3.0 million for the year ended December 31, 2025. This was primarily driven by a favorable change in the fair value of our warrant liability, partially offset by a decrease of earned interest income during the year as a result of lower average cash balances available for interest-bearing accounts.

Liquidity and Capital Resources

Sources of Liquidity

Since our formation through December 31, 2020, we have funded our operations with the sale of common and preferred stock, convertible notes and from a loan from our Chief Executive Officer and principal stockholder.

As a result of our initial public offering ("IPO"), on July 13, 2021 we began trading on the Nasdaq Capital Market under the symbol "UNCY", and on July 15, 2021 we received approximately $22.3 million in net proceeds after deducting the underwriting discounts, commissions and offering expenses. We have used the net proceeds from the IPO to complete pre-clinical and clinical studies, submit regulatory filings to the FDA, and for general and corporate purposes, including hiring additional management and conducting market research and other commercial planning.

Future revenue streams may consist of collaboration or licensing revenue as well as product sales.

On March 3, 2023, we entered into a securities purchase agreement with certain healthcare-focused institutional investors that may provide up to $130.0 million in gross proceeds through a private placement and that included initial upfront funding of $30.0 million.

On March 13, 2024, we entered into a securities purchase agreement with certain accredited investors to provide $50 million in gross proceeds through a private placement. Pursuant to the securities purchase agreement, we issued institutional purchasers $50.0 million in shares of Series B Convertible Preferred Stock. We received $46.2 million in net proceeds.

On November 13, 2024, we entered into a sales agreement, with Guggenheim Securities, LLC pursuant to which, we may offer and sell shares of common stock having an aggregate offering price of up to $50.0 million, subject to certain limitations and in accordance with the terms of the sales agreement, from time to time through or to Guggenheim Securities, LLC acting as sales agent or principal. On November 14, 2025, the Company entered into an Amendment No. 1 to sales agreement with Guggenheim Securities LLC to increase the number of shares that may be sold under the sales agreement to $100,000,000 (collectively with the November 13, 2024 sales agreement, the "Sales Agreement"). During the period from October 1, 2025 through December 31, 2025, the Company sold 1,263,882 shares of common stock pursuant to the Sales Agreement, at an average price of $5.77 per share and paid $0.2 million in commissions, resulting in net proceeds to the Company of approximately $6.6 million. During the year ended December 31, 2025, the Company sold 9,310,618 shares of common stock pursuant to the Sales Agreement, at an average price of $5.40 per share and paid $1.4 million in commissions, resulting in net proceeds to the Company of approximately $45.2 million.

Future Funding Requirements

We have incurred net losses since our inception. For the year ended December 31, 2025, we had a net loss of $26.6 million, and we expect to incur substantial additional losses in future periods. As of December 31, 2025, we had an accumulated deficit of $127.8 million.

We anticipate that our current cash will be sufficient to fund our operations for more than 12 months from the date of this report.

We expect to continue incurring losses in the future and will be required to raise additional capital in the future to complete our clinical trials, pursue product development initiatives and penetrate markets for the sale of our products. We believe that we will continue to have access to capital resources through possible equity offerings, debt financings, corporate collaborations or other means. There can be no assurance that we will be able to obtain additional financing on terms acceptable to us, on a timely basis or at all. If we are unable to secure additional capital, we may be required to curtail any clinical trials and development of new or existing products and take additional measures to reduce expenses in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. Based on our current level of expenditures, we believe that we have sufficient resources such that there is not substantial doubt about our ability to continue operations for at least one year after the date that these financial statements are available to be issued.

We anticipate that we will need to raise substantial additional capital, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug discovery efforts, pre-clinical development activities, laboratory testing and clinical trials for our current product candidates and future product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our current product candidates and future product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our current product candidates and future product candidates, if they receive marketing approval;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our current product candidates and future product candidates and, ultimately, the sale of our products, following FDA approval;
- the impact, if any, of the coronavirus pandemic on our business operations;
- our ability to access capital;
- our implementation of operational, financial and management systems; and
- the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development of any of our current product candidates or future product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments or engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders.

Adequate funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials or we may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves. If we are required to enter into collaborations and other arrangements to supplement our funds, we may have to give up certain rights that limit our ability to develop and commercialize our product candidates or may have other terms that are not favorable to us or our stockholders, which could materially affect our business and financial condition.

Summary of Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods presented below (in thousands):

	Years ended December 31,	
	2024	**2025**
Net cash (used in) provided by:		
Operating activities	$ (28,575)	$ (31,317)
Investing activities	(72)	(12,095)
Financing activities	45,088	46,468
Net increase in cash and cash equivalents	$ 16,441	$ 3,056

Cash Flows from Operating Activities

Net cash used in operating activities was $31.3 million for the year ended December 31, 2025. Cash used in operating activities was primarily due to the use of funds for development costs associated with our drug candidates, labor costs, consulting services, and other corporate expenditures for investor relations, compliance, and legal services. We incurred a net loss of $26.6 million after including the effect of non-cash adjustments for stock compensation and change in fair value of our warrant liability.

Net cash used in operating activities was $28.6 million for the year ended December 31, 2024. Cash used in operating activities was primarily due to the use of funds for development costs associated with our drug candidates, labor costs, consulting services, and other corporate expenditures for investor relations, compliance, and legal services. We incurred a net loss of $36.7 million after including the effect of non-cash adjustments for stock compensation and change in fair value of our warrant liability.

Cash Flows from Investing Activities

Net cash used in investing activities was $12.1 million for the year ended December 31, 2025 and was due primarily to the purchase of marketable securities.

Net cash used in investing activities was $72,000 for the year ended December 31, 2024 and was due to the purchase of furniture and fixtures for our corporate office.

Cash Flows from Financing Activities

Net cash provided by financing activities was $46.5 million during the year ended December 31, 2025, due primarily to sales made under the sales agreement with Guggenheim Securities LLC dated November 13, 2024 as amended by Amendment No. 1 thereto dated November 14, 2025.

Net cash provided by financing activities was $45.1 million during the year ended December 31, 2024 due primarily to the private placement financing agreement we signed on March 13, 2024 and sales made under the sales agreement with Guggenheim Securities LLC dated November 13, 2024, partially offset by dividends paid to preferred stockholders.

Off-Balance Sheet Arrangements

As of December 31, 2025 and through the filing date of this Annual Report on Form 10-K, we do not have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We consider our critical accounting policies and estimates to be related to debt and equity classification, warrant liabilities, research and development, and stock-based compensation. There have been no other material changes to our critical accounting policies and estimates during the year ended December 31, 2025 from those used for the year ended December 31, 2024. The below policies represent our critical accounting policies.

Debt and Equity Classification

In conjunction with the issuance of Series A-1 Preferred Stock in March 2023, and in conjunction with the issuance of Series B-1 Preferred Stock in March 2024, we initially account for the preferred stock as temporary or mezzanine equity. The Series A-1 and Series B-1 Preferred Stock do not fall within the scope of ASC 480, *Distinguishing Liabilities from Equity*, do not contain any embedded derivatives that require bifurcation, and are not classified as liabilities. However, as the Series A-1 and Series B-1 Preferred Stock, at issuance, are contingently redeemable upon the occurrence of an event that is not solely within our control, they are required to be initially classified as mezzanine equity and measured at the amount of net proceeds received. As the Series A-1 and Series B-1 Preferred Stock are not currently redeemable or probable of becoming redeemable, no subsequent remeasurement is required.

Warrant Liabilities

In conjunction with the issuance of Series A-1 Preferred Stock (see Note 10), we established a warrant liability as of March 3, 2023, representing the fair value of warrants that may be issued, subject to shareholder approval, upon conversion of the Series A-1 Preferred Stock. We account for these warrants as liabilities (in accordance with ASC 480, *Distinguishing Liabilities from Equity*) on the balance sheets as a result of certain redemption clauses that are not within the control of the Company. The warrant liabilities are initially measured at fair value, resulting in an implied discount on the related preferred stock financing arrangement (recognized as a partial offset to the carrying value of the Series A-1 Preferred Stock), and are remeasured at fair value each reporting period. Changes in the fair value of the warrant liabilities are recognized in earnings during each period. The warrant liabilities are measured using Level 3 fair value inputs. S*ee Note 10 to our audited financial statements included elsewhere in this Annual Report on Form 10-K for a description of warrant liabilities and the related valuations*

Research and Development

We expense costs when incurred related to the research and development associated with the design, development and testing of product candidates, as well as acquisition of product candidates or compounds. Research and development expenses include fees paid to third parties to conduct certain research and development activities on our behalf, consulting costs, costs for laboratory supplies, product acquisition and license costs, certain payroll and personnel-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expenses for our research and product development employees. We expense both internal and external research and development expenses as they are incurred.

Stock-Based Compensation

We account for stock-based compensation for all share-based payments made to employees and non-employees by estimating the fair value on the date of grant and recognizing compensation expense over the requisite service period on a straight-line basis. We recognize forfeitures related to stock-based compensation as they occur. We estimate the fair value of stock options using the Black-Scholes option-pricing model. The Black-Scholes model requires the input of subjective assumptions, including expected common stock volatility, expected dividend yield, expected term, risk-free interest rate, and the public market closing price of the Company's underlying common stock on the date of grant.

JOBS Act Accounting Election

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We have chosen to take advantage of the extended transition periods available to emerging growth companies under the JOBS Act for complying with new or revised accounting standards until those standards would otherwise apply to private companies provided under the JOBS Act. As a result, our financial statements may not be comparable to those of companies that comply with public company effective dates for complying with new or revised accounting standards.

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including, without limitation, (i) providing an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with the requirement adopted by the Public Company Accounting Oversight Board ("PCAOB") regarding the communication of critical audit matters in the auditor's report on financial statements. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Recent Accounting Pronouncements

See the section titled "Summary of Significant Accounting Policies—Recent Accounting Pronouncements" in Note 2 to our audited financial statements included elsewhere in this Annual Report on Form 10-K for additional information.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information required by this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

UNICYCIVE THERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Unicycive Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Unicycive Therapeutics, Inc. (the "Company") as of December 31, 2024 and 2025, and the related statements of operations and comprehensive loss, mezzanine equity and stockholders' (deficit) equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2025, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ GRASSI & CO., CPAs, P.C.

We have served as the Company's auditor since 2023.

Jericho, New York
March 30, 2026

Unicycive Therapeutics, Inc.
Balance Sheets
(In thousands, except for share and per share amounts)

	As of December 31, 2024	As of December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 26,142	$ 29,198
Prepaid expenses and other current assets	4,806	7,692
Marketable securities	-	12,071
Total current assets	30,948	48,961
Right of use asset, net	645	108
Property and equipment, net	75	66
Total assets	$ 31,668	$ 49,135
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,058	$ 383
Accrued liabilities	3,562	1,523
Warrant liability	18,936	16,915
Operating lease liability - current	564	117
Total current liabilities	24,120	18,938
Operating lease liability – long term	117	-
Total liabilities	24,237	18,938
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Series A-2 Prime preferred stock, $0.001 par value per share – 21,388.01 Series A-2 Prime shares authorized at December 31, 2024, and December 31, 2025; 6,150.21 and 2,265 Series A-2 Prime shares issued and outstanding at December 31, 2024, and December 31, 2025, respectively	-	-
Series B-2 preferred stock, $0.001 par value per share – 50,000 Series B-2 shares authorized at December 31, 2024, and December 31, 2025; 3,000 and zero Series B-2 shares issued and outstanding at December 31, 2024, and December 31, 2025, respectively	-	-
Preferred stock, $0.001 par value per share— 10,000,000 shares authorized at December 31, 2024, and December 30, 2025; zero shares issued and outstanding at December 31, 2024, and December 31, 2025	-	-
Common stock, $0.001 par value per share – 400,000,000 shares authorized at December 31, 2024, and December 31, 2025; 11,384,236 and 22,114,245 shares issued and outstanding at December 31, 2024, and December 31, 2025, respectively	11	22
Accumulated other comprehensive loss	-	(1)
Additional paid-in capital	108,690	158,001
Accumulated deficit	(101,270)	(127,825)
Total stockholders' equity	7,431	30,197
Total liabilities and stockholders' equity	$ 31,668	$ 49,135

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.
Statements of Operations and Comprehensive Loss
(In thousands, except for share and per share amounts)

	Year Ended December 31, 2024	Year Ended December 31, 2025
Operating expenses:		
Research and development	$ 20,014	$ 9,121
General and administrative	12,103	20,396
Total operating expenses	32,117	29,517
Loss from operations	(32,117)	(29,517)
Other income (expenses):		
Interest income	1,261	1,012
Interest expense	(71)	(71)
Change in fair value of warrant liability	(5,802)	2,021
Total other income (expenses)	(4,612)	2,962
Net loss	(36,729)	(26,555)
Other comprehensive loss:		
Unrealized loss on marketable securities, net	-	(1)
Net comprehensive loss	$ (36,729)	$ (26,556)
Dividend to Series B-1 preferred stockholders	(1,095)	-
Net loss attributable to common stockholders	$ (37,824)	$ (26,555)
Net loss per share attributable to common stockholders, basic and diluted	$ (5.65)	$ (1.67)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	6,698,513	15,886,876

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.
Statements of Mezzanine Equity and Stockholders' (Deficit) Equity
(In thousands, except share amounts)

	Series B-1 Preferred Stock		Common Stock		Series A-2 Preferred Stock		Series A-2 Prime Preferred Stock		Series B-2 Preferred Stock		Additional Paid-In	Accumulated	Stockholders' (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2023	-	$ -	3,475,605	$ 4	43,649	$ -	-	$ -	-	$ -	$ 60,728	$ (64,541)	$ (3,809)
Net loss	-	-	-	-	-	-	-	-	-	-	-	(36,729)	(36,729)
Issuance of Series B-1 preferred stock, net of issuance costs	50,000	46,187	-	-	-	-	-	-	-	-	-	-	-
Dividends on Series B-1 preferred stock	-		-	-	-	-	-	-	-	-	(1,095)	-	(1,095)
Exchange of Series A-2 preferred stock for Series A-2 Prime preferred stock	-	-	-	-	(43,649)	-	21,388.01	-	-	-	-	-	-
Conversion of Series A-2 Prime preferred stock into common stock	-	-	3,109,755	3	-	-	(15,237.80)	-	-	-	-	-	3
Issuance of Series B-2 preferred stock and common stock upon conversion of Series B-1 preferred stock	(50,000)	(46,187)	4,211,800	4	-	-	-	-	7,882	-	46,179	-	46,183
Conversion of Series B-2 preferred stock into common stock	-	-	488,200	-	-	-	-	-	(4,882)	-	-	-	
Issuance of common stock for cash, net of issuance costs	-	--	97,740	-	-	-	-	-	-	-	524	-	524
Issuance of common stock for exercise of options	-	-	1,136	-	-	-	-	-	-	-	4	-	4
Stock-based compensation expense	-	-	-	-	-	-	-	-	-	-	2,350	-	2,350
Balance at December 31, 2024	-	$ -	11,384,236	$ 11	-	$ -	6,150.21	$ -	3,000	$ -	$ 108,690	$ (101,270)	$ 7,431

	Common Stock		Series A-2 Prime Preferred Stock		Series B-2 Preferred Stock		Series A-3 Preferred Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Equity
Balance at December 31, 2024	11,384,236	$ 11	6,150.21	$ -	3,000	$ -	-	$ -	108,690	$ (101,270)	$ -	$ 7,431
Net loss	-	-	-	-	-	-	-	-	-	(26,555)		(26,555)
Issuance of Series A-3 preferred stock upon exercise of warrants	-	-	-	-	-	-	1,495.80	-	1,496	-	-	1,496
Conversion of Series A-2 Prime preferred stock into common stock	792,900	1	(3,885.21)	-	-	-	-	-	-	-	-	1
Conversion of Series B-2 preferred stock into common stock	300,000	-	-	-	(3,000)	-	-	-	-	-	-	-
Conversion of Series A-3 preferred stock into common stock	277,000	-	-	-	-	-	(1,495.80)	-	-	-	-	-
Issuance of common stock for vested restricted stock units	1,000	-	-	-	-	-	-	-	-	-	-	-
Issuance of common stock for cash, net of issuance costs	9,310,618	10	-	-	-	-	-	-	45,174	-	-	45,184
Unrealized loss on available-for-sale securities, net	-	-	-	-	-	-	-	-	-	-	(1)	(1)
Reverse split share adjustment	48,491	-	-	-	-	-	-	-	-	-	-	-
Stock-based compensation expense	-	-	-	-	-	-	-	-	2,641	-	-	2,641
Balance at December 31, 2025	22,114,245	$ 22	2,265	$ -	-	$ -	-	$ -	$ 158,001	$ (127,825)	$ (1)	$ 30,197

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.
Statements of Cash Flows
(In thousands)

	Year Ended December 31, 2024	Year Ended December 31, 2025
Cash flows from operating activities		
Net loss	$ (36,729)	$ (26,555)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	22	34
Stock-based compensation expense	2,350	2,641
Change in fair value of warrant liability	5,802	(2,021)
Amortization of operating lease right of use asset	406	538
Changes in assets and liabilities:		
Prepaid expense and other current assets	(820)	(2,884)
Accounts payable and accrued liabilities	790	(2,505)
Operating lease liability	(397)	(565)
Net cash used in operating activities	(28,575)	(31,317)
Cash flows from investing activities		
Purchases of marketable securities	-	(12,071)
Purchases of property and equipment	(72)	(24)
Net cash used in investing activities	(72)	(12,095)
Cash flows from financing activities		
Gross proceeds from secondary public offering	683	46,582
Commissions paid on secondary public offering		(1,398)
Deferred cost of at the market offering	(160)	-
Payments on financed insurance policies	(527)	(212)
Issuance costs related to issuance of Series B-1 preferred stock	(3,813)	-
Proceeds from issuance of Series B-1 preferred stock	50,000	-
Proceeds from exercise of warrants	-	1,496
Dividends on preferred stock	(1,095)	-
Net cash provided by financing activities	45,088	46,468
Net increase in cash and cash equivalents	16,441	3,056
Cash and cash equivalents at the beginning of the period	9,701	26,142
Cash and cash equivalents at the end of the period	$ 26,142	$ 29,198
Supplemental cash flow information		
Issuance of Series B-2 preferred stock and common stock upon conversion of Series B-1 preferred stock	$ 46,187	$ -
Deferred insurance charges included in prepaid expenses and other current assets	$ 267	$ 332
Cash paid for interest	$ 12	$ -

See accompanying notes to the financial statements

1. Organization and Description of Business

Overview

Unicycive Therapeutics, Inc. ("we", "the Company") was incorporated in the State of Delaware on August 18, 2016.

The Company in-licensed the drug candidate UNI 494 from Sphaera Pharma Pte. Ltd, a Singapore-based corporation, ("Sphaera") (Note 4). UNI 494 is a pro-drug of Nicorandill that is being developed as a treatment for acute kidney injury.

In September 2018, the Company purchased a second drug candidate, Renazorb RZB 012 and its trademark, RENALAN, and various patents from Spectrum Pharmaceuticals, Inc. ("Spectrum") (Note 4). Renazorb ("oxylanthanum carbonate") is being developed for the treatment of hyperphosphatemia in patients with Chronic Kidney Disease ("CKD").

The Company continues to evaluate the licensing of additional technologies and drugs in order to pursue development, regulatory approval, and commercialization of those products in global markets.

Liquidity

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with governmental regulations and the need to obtain additional financing to fund operations. The Company's product candidates currently under development will require significant additional research and development efforts prior to commercialization. Future revenue streams may consist of collaboration or licensing revenue as well as product sales.

The Company has incurred operating losses and negative cash flows from operations since inception and expects to continue to incur negative cash flows from operations in the future. As the Company continues its drug development activities, the operating losses are expected to increase. The Company has historically relied on private equity offerings, debt financing and loans from a stockholder to fund its operations. As of December 31, 2024 and December 31, 2025, the Company had an accumulated deficit of $101.3 million and $127.8 million, respectively.

In connection with its initial public offering ("IPO"), on July 13, 2021, the Company began trading on the Nasdaq Capital Market under the symbol "UNCY", and on July 15, 2021, received approximately $22.3 million in net proceeds after deducting the underwriting discounts, commissions and other offering expenses. The Company has used the net proceeds from the IPO to complete pre-clinical and clinical studies, prepare regulatory filings for the FDA, and for general and corporate purposes, including hiring additional management and conducting market research and other commercial planning.

On March 3, 2023, the Company entered into a securities purchase agreement with certain healthcare-focused institutional investors that may provide up to $130.0 million in gross proceeds through a private placement and that included initial upfront funding of $30.0 million in gross proceeds.

On March 13, 2024, the Company entered into a securities purchase agreement with certain healthcare-focused institutional investors to provide $50 million in gross proceeds through a private placement. Pursuant to the securities purchase agreement, the Company issued institutional investors $50 million in shares of Series B Convertible Preferred Stock. The Company received $46.2 million in net proceeds.

On November 13, 2024, the Company entered into a sales agreement, with Guggenheim Securities, LLC as amended by Amendment No. 1 thereto dated November 14, 2025 (as amended, the "Sales Agreement") pursuant to which, we may offer and sell shares of common stock having an aggregate offering price of up to $100.0 million, subject to certain limitations and in accordance with the terms of the sales agreement, from time to time through or to Guggenheim Securities, LLC acting as sales agent or principal.

During the year ended December 31, 2025, the Company sold 9,310,618 shares of common stock pursuant to a sales agreement, with Guggenheim Securities, LLC, at an average price of $5.00 per share and paid $1.4 million in commissions, resulting in net proceeds to the Company of approximately $45.2 million.

The Company expects to continue incurring losses in the future and will be required to raise additional capital in the future to complete its planned clinical trials, pursue product development initiatives and penetrate markets for the sale of its products. Management believes that the Company will continue to have access to capital resources through possible equity offerings, debt financings, corporate collaborations or other means. There can be no assurance that the Company will be able to obtain additional financing on terms acceptable to the Company, on a timely basis or at all. If the Company is unable to secure additional capital, it may be required to curtail any clinical trials and development of new or existing products and take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations. Based on the Company's currently anticipated level of expenditures, the Company believes that it has sufficient resources such that there is not substantial doubt about the ability to continue operations for at least one year after the date that these financial statements are available to be issued.

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements and accompanying notes have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP").

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the periods presented. Management believes that these estimates and assumptions are reasonable; however, actual results may differ and could have a material effect on future results of operations and financial position. Significant items subject to such estimates and assumptions include stock-based compensation, research contract progress estimates, incremental borrowing rate for leases, useful life for assets, valuation of marketable securities, equity transactions, and the valuation of warrant liabilities. Actual results may materially differ from those estimates.

Cash and Cash Equivalents

Highly liquid investments that are readily convertible to cash and have original maturities of three months or less at the time of acquisition are considered cash equivalents. As of December 31, 2025, cash and cash equivalents consist of cash deposited with banks, money market funds, investment in corporate bonds with original maturities of three months or less, and U.S. Treasury bills. As of December 31, 2024, cash and cash equivalents consist of cash deposited with banks and money market funds.

Marketable Securities

Marketable securities consist of corporate debt securities with original maturities beyond three months at the date of purchase and which mature at, or less than 12 months from, the balance sheet date. The Company classifies its investment in marketable securities as available-for-sale, as the sale of such securities may be required prior to maturity. Management determines the appropriate classification of its investments in debt securities at the time of purchase. The Company obtains pricing information from its investment manager and generally determines the fair value of investment securities using standard observable inputs, including reported trades, broker/dealer quotes, and bid and/or offers. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported as accumulated other comprehensive income (loss).The carrying value of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, the net amount of which, along with interest and realized gains and losses, is included under other income (expense) in the statements of comprehensive income (loss).

At each balance sheet date, the Company reviews its available-for-sale debt securities that are in an unrealized loss position to determine whether the unrealized loss or any potential credit losses should be recognized in the statements of operations. For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value through net income (loss). For available-for-sale securities that do not meet the above criteria, the Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the severity of the impairment, any changes in interest rates, changes to the underlying credit ratings and forecasted recovery among other factors. The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in other income, net through an allowance account. There have been no impairment or credit losses recognized during any of the periods presented.

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Warrant Liability

In conjunction with the issuance of Series A-1 Preferred Stock (see Note 9), the Company established a warrant liability as of March 3, 2023, representing the fair value of warrants that may be issued (and have since been issued), subject to shareholder approval, upon conversion of the Series A-1 Preferred Stock which was received on June 26, 2023. The Company accounts for these warrants as liabilities (in accordance with ASC 480, *Distinguishing Liabilities from Equity*) on the balance sheets as a result of certain redemption clauses that are not within the control of the Company. The warrant liability was initially measured at fair value and is remeasured at fair value each reporting period. Changes in the fair value of the warrant liability are recognized in earnings during each period. The warrant liability is measured using Level 3 fair value inputs. See Note 11 for a description of warrant liability and the related valuations.

Segment Information

The Company reports its segment information to reflect the manner in which the Company's Chief Operating Decision Maker ("CODM") reviews and assesses performance. The Company's Chief Executive Officer has the responsibility as the CODM to review and assess the performance of the Company as a whole.

The primary financial measures used by the CODM to evaluate performance and allocate resources are net (loss) income and operating (loss) income. The CODM uses net income (loss) and operating (loss) income to evaluate the performance of the Company's ongoing operations and as part of the Company's internal planning and forecasting processes. Information on net (loss) income and operating (loss) income is disclosed in the statements of operations. Segment expenses and other segment items are provided to the CODM on the same basis as disclosed in the Statements of Operations.

The CODM does not evaluate performance or allocate resources based on segment assets, and therefore such information is not presented in the notes to the financial statements.

Risks and Uncertainties

The Company operates in a dynamic and highly competitive industry and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows: ability to obtain future financing; advances and trends in new technologies and industry standards; results of clinical trials; regulatory approval and market acceptance of the Company's products; development of sales channels; certain strategic relationships; litigation or claims against the Company related to intellectual property, product, regulatory, or other matters; and the Company's ability to attract and retain employees necessary to support its growth.

The Company's general business strategy may be adversely affected by any such economic, volatile business environments and continued unstable or unpredictable economic and market conditions.

Any product candidates developed by the Company will require approvals from the FDA or other international regulatory agencies prior to commercial sales. There can be no assurance that the Company's current product candidates or any future product candidates will receive the necessary approvals. If the Company is denied approval, approval is delayed or the Company is unable to maintain approval, it could have a materially adverse impact on the Company.

The Company has expended and will continue to expend substantial funds to complete the research, development and clinical testing of its product candidates. The Company also will be required to expend additional funds to establish commercial-scale manufacturing arrangements and to provide for the marketing and distribution of products that receive regulatory approval. The Company will require additional funds to commercialize its products. The Company is unable to entirely fund these efforts with its current financial resources. If adequate funds are unavailable on a timely basis from operations or additional sources of financing, the Company may have to delay, reduce the scope of or eliminate one or more of its research or development programs, which would materially and adversely affect its business, financial condition and operations.

The Company is dependent upon the services of its employees, consultants and other third parties.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Additions, improvements, and major renewals or replacements that substantially extend the useful life of an asset are capitalized. Repairs and maintenance expenditures are expensed as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, which range from three to seven years for lab equipment and furniture and fixtures. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the remaining lease term.

Management assesses the carrying value of property and equipment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If there is indication of impairment, management prepares an estimate of future cash flows expected to result from the use of the asset and its eventual disposition. If these cash flows are less than the carrying amount of the asset, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the estimated fair value of the asset. During the years ended December 31, 2024 and 2025, management determined there were no impairments of the Company's property and equipment.

Leases

The Company determines whether a contract is, or contains, a lease at inception. Right-of-use assets represent the Company's right to use an underlying asset during the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The Company records the right-of-use asset at the amount of the lease liability plus any prepaid rent, and initial direct costs, less any lease incentives and accrued rent. Lease liabilities are recognized at lease commencement based upon the estimated present value of unpaid lease payments over the lease term. The right-of-use assets are reviewed for impairment whenever events or changes in circumstances exist that indicate the carrying amount may not be recoverable. The Company uses its incremental borrowing rate based on the information available at lease commencement in determining the present value of unpaid lease payments.

Fair Value of Financial Instruments

The Company's financial instruments include the cash and cash equivalents, investment in marketable securities, accounts payable, accrued liabilities, and warrant liabilities.

Fair value is defined as the price that would be received for sale of an asset or paid for transfer of a liability, in an orderly transaction between market participants at the measurement date. GAAP establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The fair value hierarchy contains the following levels:

- Level 1 — defined as observable inputs based on unadjusted quoted prices for identical instruments in active markets;
- Level 2 — defined as inputs other than Level 1 that are either directly or indirectly observable in the marketplace for identical or similar instruments in markets that are not active; and
- Level 3 — defined as unobservable inputs in which little or no market data exists where valuations are derived from techniques in which one or more significant inputs are unobservable.

The fair value of the warrant liability is determined using a Black Scholes model with parameters including (i) the exercise price of the warrants, (ii) the price of the underlying security, (iii) the time to expiration, or expected term, (iv) the expected volatility of the underlying security, (v) the risk-free rate, and (vi) estimated probability assumptions surrounding the achievement by the Company of technical milestones associated with regulatory and commercial progress.

These valuation techniques involve management's estimates and judgment based on unobservable inputs and are classified in Level 3. The fair value estimates may not be indicative of the amounts that would be realized in a market exchange. Additionally, there may be inherent uncertainties or changes in the underlying assumptions used, which could significantly affect the current or future fair value estimates. Generally, a significant increase (decrease) in the probabilities of shareholder approval and the achievement of technical milestones would have resulted in a significantly higher (lower) fair value measurement; however, changes in other inputs such as expected term and price of the underlying common stock will have a directionally opposite impact on fair value measurement.

The following tables present the approximate value of assets and liabilities measured at fair value on a recurring basis within the Company's balance sheets as of December 31, 2025 by the fair value hierarchy (in thousands):

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Cash and cash equivalents	$ 29,198	$ -	$	$ 29,198
Total cash and cash equivalents at fair value	$ 29,198	$ -	$	$ 29,198

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Corporate bonds	$ -	$ 12,071	$	$ 12,071
Total marketable securities at fair value	$ -	$ 12,071	$	$ 12,071

Refer to Note 3 for disclosures related to cash equivalents and marketable securities.

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Warrant liability	$ -	$ -	$ 16,915	$ 16,915
Total liabilities at fair value	$ -	$ -	$ 16,915	$ 16,915

The following tables present the approximate value of assets and liabilities measured at fair value on a recurring basis within the Company's balance sheets as of December 31, 2024 by the fair value hierarchy (in thousands):

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Cash and cash equivalents	$ 26,142	$ -	$	$ 26,142
Total cash and cash equivalents at fair value	$ 26,142	$ -	$	$ 26,142

Refer to Note 3 for disclosures related to cash equivalents and marketable securities.

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Warrant liability	$ -	$ -	$ 18,936	$ 18,936
Total liabilities at fair value	$ -	$ -	$ 18,936	$ 18,936

The following table summarizes the changes in fair value of the warrant liability classified in Level 3. Gains and losses reported in this table include changes in fair value that are attributable to unobservable inputs (in thousands):

	Year Ended December 31, 2025
Fair value at January 1, 2025	$ 18,936
Change in fair value of warrants	(2,021)
Fair value at December 31, 2025	$ 16,915

	Year Ended December 31, 2024
Fair value at January 1, 2024	$ 13,134
Change in fair value of warrants	5,802
Fair value at December 31, 2024	$ 18,936

The expense relating to the change in fair value of the warrant liability of $5.8 million and income of $2.0 million for the years ended December 31, 2024 and December 31, 2025, respectively, is included in other income (expenses) in the statements of operations.

ASC 820, *Fair Value Measurement and Disclosures* requires all entities to disclose the fair value of financial instruments, both assets and liabilities, for which it is practicable to estimate fair value. As of December 31, 2024, and December 31, 2025, the recorded values of cash and cash equivalents, accounts payable, and accrued liabilities approximated fair value due to the short-term nature of the instruments. Cash and cash equivalents, accounts payable, and accrued liabilities are Level 1 financial instruments.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. The cash and cash equivalents the Company uses to satisfy working capital and operating expense needs are held in accounts at various financial institutions. Cash balances may at times exceed federally insured limits. Cash and cash equivalents could be adversely impacted, including the loss of uninsured deposits and other uninsured financial assets, if one or more of the financial institutions in which the Company holds its cash or cash equivalents fails or is subject to other adverse conditions in the financial or credit markets. No such losses have been incurred through December 31, 2025.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets represent costs incurred that benefit future periods. These costs are amortized over specific time periods based on the agreements.

Research and Development Expenses

Substantially all the Company's research and development expenses consist of expenses incurred in connection with the development of the Company's product candidates. These expenses include fees paid to third parties to conduct certain research and development activities on the Company's behalf, consulting costs, costs for laboratory supplies, product acquisition and license costs, certain payroll and personnel-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expenses for the Company's research and product development employees. The Company expenses both internal and external research and development expenses as incurred.

General and Administrative Expenses

General and administrative expenses represent personnel costs for employees involved in general corporate functions, including finance, accounting, legal and human resources, among others. Additional costs included in general and administrative expenses consist of professional fees for legal (including patent costs), audit and other consulting services, stock-based compensation and other general corporate overhead expenses.

Patent Costs

The Company expenses all costs as incurred in connection with patent licenses and applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are reflected in general and administrative expenses in the statements of operations.

Stock-Based Compensation

The Company accounts for stock-based compensation for all share-based payments made to employees and non-employees by estimating the fair value on the date of grant and recognizing compensation expense over the requisite service period on a straight-line basis. The Company recognizes forfeitures related to stock-based compensation as they occur. The Company estimates the fair value of stock options using the Black-Scholes option-pricing model. The Black-Scholes model requires the input of subjective assumptions, including expected common stock volatility, expected dividend yield, expected term, risk-free interest rate, and the public market closing price of the Company's underlying common stock on the date of grant.

Income Taxes

The Company accounts for corporate income taxes in accordance with GAAP as stipulated in ASC740, Income Taxes, ("ASC 740"). This standard entails the use of the asset and liability method of computing the provision for income tax expense. Current tax expense results from corporate tax payable at the Federal and California jurisdictions for the Company, which relates to the current accounting period. Deferred tax expense results primarily from temporary differences between financial statement and tax return reporting, which result in additional tax payable in future periods. Deferred tax assets and liabilities are determined based on the differences between the financial statement basis and tax basis of assets and liabilities using enacted tax rates and law. Net future tax benefits are subject to a valuation allowance when management expects that it is more-likely-than-not that some portion or all of the deferred tax assets will not be realized.

Current and non-current tax assets and liabilities are based upon an estimate of taxes refundable or payable for each of the jurisdictions in which the Company is subject to tax. In the ordinary course of business there is inherent uncertainty in quantifying income tax positions. The Company assess income tax positions and record the largest amount of tax benefit with a greater than 50% likelihood of being realized upon ultimate settlement with a taxing authority that has full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, no tax benefit is recognized in the financial statements. The Company's policy is to recognize interest or penalties related to income tax matters in income tax expense.

Comprehensive Loss

Accumulated other comprehensive loss includes unrealized gains and losses on securities available for sale, and is recognized as separate components of stockholders' equity, As of December 31, 2025, comprehensive loss of $1,000 related to marketable securities was recorded.

Net Income (Loss) per Share

Basic and diluted net income (loss) per share is presented in conformity with the two-class method required for participating securities. Basic and diluted net income (loss) for common stock and for preferred stock is computed by dividing the sum of distributed earnings and undistributed earnings for each class of stock by the weighted average number of shares outstanding for each class of stock for the period. Diluted net income (loss) per share includes potentially dilutive securities outstanding for the period. See Note 12 for reconciliations of basic and diluted net income (loss) per share.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective are not expected to have a material impact on the Company's financial position or results of operations upon adoption.

Income Taxes Disclosures – In December 2023, the FASB issued ASU No. 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." ASU 2023-09 requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. The Company adopted this standard prospectively for the year ended December 31, 2025. The adoption of the standard impacted the 2025 income tax disclosures.

Accounting pronouncements pending adoption

On November 4, 2024, the FASB issued ASU No. 2024-03, Expense Disaggregation Disclosures ("ASU 2024-03"). ASU 2024-03 amends ASC 220, Comprehensive Income to expand income statement expense disclosures and require disclosure in the notes to the financial statements of specified information about certain costs and expenses. ASU 2024-03 is required to be adopted for fiscal years commencing after December 15, 2026, with early adoption permitted. The Company is currently evaluating the impact of adopting the standard on its financial statements.

3. Cash, Cash Equivalents, and Marketable Securities

The following table summarizes the Company's investments as of December 31, 2025 (in thousands):

	Amortized Cost Basis	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Cash	$ 24,172	$ -	$ -	$ 24,172
U.S. Treasury Bills	3,449	-	-	3,449
Money Market	1,577			1,577
Investments in corporate bonds	12,072	-	(1)	12,071
Total cash, cash equivalents and investments in marketable securities	$ 41,270	$ -	$ (1)	$ 41,269

The Company classifies its investments in corporate bonds as available-for-sale. Unrealized gains and losses on these securities are included as a component of comprehensive income (loss). The Company did not hold any investments in corporate bonds as of December 31, 2024.

On December 31, 2025, the remaining contractual maturities of all the Company's available-for-sale investments were less than twelve months. As of December 31, 2025, the Company has not established an allowance for credit losses for any of its available-for-sale securities.

4. Significant Agreements

With regards to manufacturing, testing and potential commercial supply of oxylanthanum carbonate, on October 31, 2020, the Company entered into an agreement with Shilpa Medicare Ltd ("Shilpa") based in India. Pursuant to the Agreement, Shilpa provides certain development, manufacturing, supply and other CMC-related services related to the development and commercialization of oxylanthanum carbonate ("OLC").

In June 2024, the Company entered into the First Amendment to Manufacturing and Supply Agreement with Shilpa (the "Amendment") in anticipation of an increased manufacturing demand for OLC. Pursuant to the Amendment, the Company has agreed to make a binding purchase order for tablets of OLC and Shilpa has agreed to deliver such order by September 30, 2025. In addition, the Company has agreed to order additional tablets for delivery between December 31, 2025, and September 30, 2026. Further, the Company has agreed to make certain milestone payments and to provide certain funding to Shilpa for a new manufacturing line. The initial term of the Agreement shall continue until the eighth (8th) anniversary of the date of receipt by the Company of FDA approval of its NDA of OLC (the "Initial Term"). Following the Initial Term, the Agreement shall continue in effect for consecutive periods of four (4) years each unless earlier terminated pursuant to the terms of the Agreement.

In October 2017, the Company entered into an exclusive license agreement with Sphaera, a stockholder, for the rights to further develop the drug candidate, UNI 494, for commercialization. No payments were made upon execution of the agreement but payments for $50,000 will be due commencing with the initiation by the Company of a second clinical trial and $50,000 on completion of such trial. If the FDA accepts a NDA application submitted by the Company for the product, the Company will pay Sphaera $1.65 million. Upon commercialization and sale of the drug product, royalty payments will also be payable quarterly to Sphaera equal to 2% of net sales in the preceding quarter.

In September 2018, the Company entered into an Assignment and Asset Purchase Agreement with Spectrum Pharmaceuticals, Inc. ("Spectrum Agreement") pursuant to which the Company purchased certain assets from Spectrum, including Spectrum's right, title, interest in and intellectual property related to Renazorb RZB 012, also known as RENALAN™ ("Renalan") and RZB 014, also known as SPI 014 ("SPI" and together with Renalan, the "Compounds"), to further develop and commercialize oxylanthanum carbonate and related compounds. In partial consideration for the Spectrum Agreement, the Company issued 31,366 shares of common stock to Spectrum valued at approximately $4,000 which represented four percent of the Company on a fully-diluted basis at the date of the execution of the Spectrum Agreement. The Spectrum Agreement has an anti-dilution provision, which provides that Spectrum maintain its ownership interest in the Company at 4% of the Company's shares on a fully-diluted basis. Fully-diluted shares of common stock for purposes of the oxylanthanum carbonate Purchase Agreement assumes conversion of any security convertible into or exchangeable or exercisable for common stock or any combination thereof, including any common stock reserved for issuance under a stock option plan, restricted stock plan, or other equity incentive plan approved by the Board of Directors of the Company immediately following the issuance of additional shares of the Company's common stock (but prior to the issuance of any additional shares of common stock to Spectrum). Spectrum's ownership shall not be subject to dilution until the earlier of thirty-six months from the first date the Company's stock trades on a public market, or the date upon which the Company attains a public market capitalization of at least $50 million. On July 13, 2021, the Company's initial public offering resulted in a public market capitalization of at least $50 million, and as a result the Company was required to issue 43,838 anti-dilution shares of common stock. This issuance represented the final anti-dilution calculation required under the Spectrum Agreement, and no further anti-dilution shares will be issued. The Company calculated the fair value of the shares and recognized $2.2 million to research and development expenses as cost to issue those shares during the third quarter of 2021. In the event an NDA filing for oxylanthanum carbonate is accepted by the FDA, the Company will be required to pay $0.2 million to Altair Nanomaterials, Inc., ("Altair") in accordance with the Spectrum Agreement. In addition, in the event FDA approval for oxylanthanum carbonate is received, the Company will be required to pay $4.5 million to Altair. The Company is also required to pay Spectrum 40% of all the Company's sublicense income for any sublicense granted to certain sublicensees during the first 12 months after the Closing Date (as that term is defined in the Spectrum Agreement) and 20% of all other sublicense income. The Company's payment obligations to Spectrum will expire on the twentieth (20th) anniversary of the Closing Date of the Spectrum Agreement. In August 2022, the Company received an upfront payment of approximately $1.0 million resulting from a sublicense development agreement with Lee's Pharmaceutical (HK) Limited. In February 2023, the Company received an upfront payment of approximately $0.7 million resulting from a sublicense development agreement with Lotus International Pte Ltd. The payment represents sublicense income as described in the Spectrum Agreement, and 20% of the amount received has been accrued as an R&D expense in the accompanying statements of operations for the year ended December 31, 2025.

On January 6, 2022, the Company entered into a Master Services Agreement with Quotient Sciences Limited ("Quotient"), a UK based company that provides drug development and analysis services, for the purpose of performing clinical research in support of UNI-494. The initial budget for the study is approximately $3.7 million, and subsequent revisions reduced the overall budget to $2.9 million. Related payments totaling approximately $2.9 million have been paid to Quotient as of December 31, 2025, approximately $2.9 million of related expense has been recorded, and there is no prepaid balance in the accompanying balance sheets as of December 31, 2024 and December 31, 2025, respectively.

On April 10, 2023, the Company entered into an agreement with Inotiv that provides preclinical trial and related services, for the purpose of performing research in support of UNI-494. The budget for these services is approximately $2.9 million. Approximately $2.9 million has been paid to Inotiv as of December 31, 2025 and there is no prepaid balance in the accompanying balance sheets as of December 31, 2024 and December 31, 2025, respectively.

On July 14, 2022, the Company entered into a license agreement with Lee's Pharmaceutical (HK) Limited. Under the terms of the agreement, Lee's Pharmaceutical will be responsible for development, registration filing and approval for oxylanthanum carbonate in China, Hong Kong, and certain other Asian markets. In addition, Lee's Pharmaceutical will have sole responsibility for the importation of the drug product from the Company and for the costs of commercialization of oxylanthanum carbonate in the licensed territories. The Company has received an upfront payment of $1.0 million, expects to receive up to $1.0 million in milestone payments upon product launch in China and will be eligible for tiered royalties of between 7% and 10% upon achievement of prespecified regulatory and commercial achievements.

On February 1, 2023, the Company entered into a license agreement with Lotus International Pte Ltd. ("Lotus"). Under the terms of the agreement, Lotus will be responsible for development, registration filing and approval for oxylanthanum carbonate in the licensed territory of South Korea. In addition, Lotus will have sole responsibility for the importation of the drug product from the Company and for the costs of commercialization of oxylanthanum carbonate in the licensed territory. The Company has received an upfront payment of $0.7 million, may receive up to $3.7 million in future milestone payments and will be eligible for tiered royalties upon achievement of specified commercial achievements.

On June 29, 2023 and October 26, 2023, the Company entered into services agreements with Shilpa related to NDA filing support for oxylanthanum carbonate. The agreements provide for total payments of up to $4.5 million, and the Company has made $4.5 million in payments pursuant to the agreements as of December 31, 2025.

5. Balance Sheet Components

Prepaid expenses and other current assets as of December 31, 2024 and December 31, 2025 consisted of the following (in thousands):

	As of December 31, 2024	As of December 31, 2025
Prepaid directors' and officers' liability insurance premiums	$ 263	$ 332
Prepaid drug manufacturing supply costs	3,604	6,189
Other	939	1,171
Total	$ 4,806	$ 7,692

Property and equipment as of December 31, 2024 and December 31, 2025 consisted of the following (in thousands):

	As of December 31, 2024	As of December 31, 2025
Leasehold improvements	$ 49	$ 65
Lab equipment	26	26
Furniture and fixtures	39	47
Subtotal	114	138
Less accumulated depreciation	(39)	(72)
Net	$ 75	$ 66

Accounts payable as of December 31, 2024 and December 31, 2025 consisted of the following (in thousands):

	As of December 31, 2024	As of December 31, 2025
Trade accounts payable	$ 966	$ 301
Credit card liability	92	82
Total	$ 1,058	$ 383

Accrued liabilities as of December 31, 2024 and December 31, 2025 consisted of the following (in thousands):

	As of December 31, 2024	As of December 31, 2025
Accrued labor costs	$ 1,910	$ 329
Accrued drug development costs	1,258	753
Other	394	441
Total	$ 3,562	$ 1,523

6. Operating Lease

The Company leases office space under an operating lease. In December 2021, the Company entered into a lease agreement for 2,367 square feet of office space commencing December 1, 2021. The initial lease term was for two years, and there was an option to extend the lease for an additional year. On March 3, 2023, the Company expanded its leased space through a lease amendment by an additional 2,456 square feet commencing March 15, 2023. The term of the amended lease is for three years with an option to extend the lease for three additional years. On June 28, 2024, the Company further expanded its leased space through a lease amendment by an additional 2,581 square feet commencing July 15, 2024. The term of the amended lease unifies with the current expiration of the lease which is March 31, 2026.

The lease amendment represents a modification of the original lease, and the Company evaluated the new agreement under ASC 842, Leases. The Company classified the lease as an operating lease and, on July 15, 2024, determined that the present value of the lease was approximately $1.0 million using an estimated incremental borrowing rate of 10%. During the years ended December 31, 2024 and December 31, 2025, the Company reflected amortization of right-of-use asset of approximately $0.4 million and $0.5 million, respectively, resulting in a right-of-use asset balance of approximately $0.1 million at December 31, 2025.

During the years ended December 31, 2024 and December 31, 2025, the Company made cash payments on the lease of $0.5 million and $0.6 million, respectively towards the lease liabilities. As of December 31, 2025, the total lease liability was approximately $0.1 million

As of December 31, 2025, maturities of the Company's lease liabilities are as follows (in thousands):

	Operating Lease
Year ending December 31, 2026	$ 118
Total lease payments	118
Less imputed interest rate / present value discount	(1)
Present value of lease liability	117
Less current portion	(117)
Long term portion	$ -

In November 2025, the Company entered into a lease agreement for 10,734 square feet of office space commencing on February 1, 2026. The initial lease term is for one and a half years, and there is an option to extend the lease for an additional year. The Company is evaluating the new agreement under ASC 842, Leases.

7. Commitments and Contingencies

Contingencies

The Company is subject to claims and legal proceedings that arise in the ordinary course of business. Such matters are inherently uncertain, and there can be no guarantee that the outcome of any such matter will be decided favorably to the Company or that the resolution of any such matter will not have a material adverse effect upon the Company's financial statements. On August 15, 2025, a putative shareholder class action complaint captioned *Elkhodari v. Unicycive Therapeutics, Inc., et al.*, Case No. 3:25-cv-06923-JD (the "Securities Class Action"), was filed in the U.S. District Court for the Northern District of California ("Northern District of California"), naming the Company and certain current officers and/or directors of the Company as defendants. The lawsuit generally alleges that the Company made material misrepresentations and/or omissions of material fact relating to the Company's manufacturing of oxylanthanum carbonate ("OLC") and the approval prospects of its New Drug Application for OLC for the treatment of hyperphosphatemia in CKD patients on dialysis in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder. The putative class action is brought on behalf of persons or entities who purchased or otherwise acquired the Company's securities between March 29, 2024, and June 27, 2025, inclusive, and seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorneys' fees. On January 27, 2026, Plaintiff filed an amended complaint. On March 13, 2026, defendants filed their motion to dismiss the amended complaint.

On October 30 and November 7, 2025, two purported stockholders of the Company filed derivative complaints in the Northern District of California against certain of the Company's current officers and directors (collectively, the "Derivative Actions"). The Company is named as a nominal defendant. The complaints are based on the same alleged misconduct as in the Securities Class Action. The complaints assert state law claims on behalf of the Company against the individual defendants for breach of fiduciary duty, unjust enrichment, gross mismanagement, and waste of corporate assets, and federal law claims under Section 14(a) of the Exchange Act. On November 20, 2025, the Court issued an order relating the Derivative Actions to the Securities Class Action. The Derivative Actions seek unspecified damages on behalf of the Company, corporate governance reforms, disgorgement and restitution, and an award of costs and expenses, including attorneys' fees.

On March 12, 2026, a purported stockholder made a demand on the Company's Board of Directors to commence a civil action against certain of the Company's current and former officers and directors for breaching their fiduciary duties based on the same alleged misconduct as alleged in the above-mentioned Securities Class Action and Derivative Actions (the "Demand").

At this early stage of the proceedings, the Company is unable to make any prediction regarding the outcome of the Securities Class Action, the Derivative Actions, or the Demand.

It is possible that additional lawsuits will be filed or allegations will be made by stockholders with respect to these same or other matters also naming the Company and/or our officers and directors as defendants. The Company intends to vigorously defend against the claims brought by the plaintiffs in each of these matters.

Such lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of the pending lawsuits and any other related lawsuits is necessarily uncertain. The Company could be forced to expend significant resources and may incur substantial legal fees and costs in defending against the pending lawsuits and any other related lawsuits, and we may not prevail. Monitoring, initiating and defending against legal actions is time-consuming for our management, is likely to be expensive, and may detract from the ability to fully focus internal resources on business activities. Additionally, the Company may not be successful in having any such lawsuits dismissed or settled within the limits of insurance coverage. Given the early stage of these lawsuits and the inherent uncertainty of litigation, the Company cannot predict how long it may take to resolve the pending lawsuits or the potential outcome or possible amount of any damages. As such, we currently are unable to reasonably estimate the possible losses or a range of possible losses that may result from these matters, if any. Expenses associated with the pending lawsuits and any potential related lawsuits could be material to the financial statements if we do not prevail in the defense of such lawsuits, or even if we do prevail.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications, including for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but that have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations.

The Company believes that the likelihood of conditions arising that would trigger these indemnities is remote and, historically, the Company had not made any significant payment under such indemnification provisions. Accordingly, the Company has not recorded any liabilities relating to these agreements. However, the Company may record charges in the future as a result of these indemnification obligations.

Additionally, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at the Company's request in such capacity. The indemnification period covers all pertinent events and occurrences during the director's or officer's service.

Employee Benefit Plan

In December 2021, the Company implemented a 401(k) Plan which covers all eligible employees of the Company (the "401(k) Plan"). Employer matching contributions are immediately 100% vested. The Company's 401(k) Plan provides that the Company match each participant's contribution at 100% up to 4% of the employee's eligible compensation. Company contributions to the 401(k) Plan totaled approximately $136,000 and $180,000 for the years ended December 31, 2024 and December 31, 2025, respectively.

8. Stockholders' Equity

Authorized Common Stock

The Company is authorized to issue up to 400,000,000 shares of common stock at par value of $0.001 per share.

Reverse Stock Split

On June 18, 2025, the Company filed a certificate of amendment to its certificate of incorporation with the Secretary of State of the State of Delaware to effectuate a 1-for-10 reverse stock split. The Company's common stock began trading on a split-adjusted basis at the opening of trading on the Nasdaq Capital Market on June 20, 2025. When the reverse stock split became effective, every 10 shares of common stock were automatically reclassified and combined into one share of common stock. No fractional shares were issued as a result of the split. Stockholders who would otherwise have received a fractional share automatically had their fractional interests rounded up to the next whole share, after aggregating all the fractional interests of a holder resulting from the split. The reverse stock split affected all stockholders uniformly and will not change any stockholder's percentage ownership interest or any stockholder's proportionate voting power, except for immaterial changes that may result from the treatment of fractional shares. The split did not change the number of authorized shares of common stock or the par value per share of the common stock.

As a result of the reverse stock split, proportionate adjustments were made to the per share exercise prices of, and the number of shares underlying, the Company's outstanding stock options, as well as to the number of shares available for future awards granted under the Company's stock incentive plans. In addition, proportionate adjustments were made to the per share exercise prices of, and the number of shares underlying, outstanding warrants to purchase shares of the Company's common stock. Further, a proportionate adjustment was made to the per share conversion price of the Company's series A-2 prime preferred stock, pursuant to its terms. All share and per share data in the accompanying financial statements have been retroactively adjusted to reflect the effect of the reverse stock split.

Issuance of Common Stock and Warrants from Initial Public Offering

During July 2021, as a result of its initial public offering, the Company issued 500,000 shares of common stock and 400,000 warrants to investors in exchange for cash at $50.00 per unit, consisting of $49.90 per share of common stock and $.0.10 per four fifths of a warrant. The warrants have a 5-year term and an exercise price of $60.00 per warrant. The underwriters exercised their option to purchase an additional 60,000 warrants, and the Company received $7,500 in proceeds.

As a result of the initial public offering, the Company's outstanding convertible notes and unpaid accrued interest were converted into 73,691 shares of common stock. Additionally, in accordance with the original terms of the warrant agreements convertible noteholders were granted a total of 18,419 common stock warrants with a 5-year term and with an exercise price of $60.00 per warrant.

The warrants from the initial public offering are equity classified. The following table summarizes activity for the Company's IPO warrants for the year ended December 31, 2025:

	Number of Shares Underlying Outstanding Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2024	478,419	60.00	1.54	-
Warrants granted	-	-	-	-
Warrants exercised	-	-	-	-
Outstanding, December 31, 2025	478,419	60.00	0.54	-

Issuance of Common Stock Upon Conversion of Series A and Series B Preferred Stock

On June 26, 2023, the Company held its annual shareholder meeting and, as a result, shareholder approval for the issuance of common shares upon the conversion of the Series A-1 Preferred Stock was obtained (see Note 9). On July 11, 2023, pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock (the "Series A Certificate of Designation"), the Company issued a total of 1,951,621 shares of common stock and 43,649 Series A-2 Preferred Stock in settlement of the auto-conversion of the Series A-1 Preferred Stock.

On March 26, 2024, the Company issued 285,000 shares of common stock upon conversion of 1,396.50 shares of Series A-2 Prime Preferred Stock.

On June 20, 2024, we held our annual stockholder meeting, and as a result, stockholder approval for the conversion of the Series B-1 Convertible Preferred Stock was obtained (see Note 10). On July 5, 2024, pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series B Convertible Preferred Stock, the Company issued 4,211,800 shares of common stock and 7,882 shares of Series B-2 preferred stock in settlement of the automatic conversion of the Series B-1 Convertible Preferred Stock.

On June 25, 2024, the Company issued 595,600 shares of common stock upon conversion of 2,918.44 shares of the Company's Series A-2 Prime Preferred Stock.

On July 23, 2024, the Company issued 355,000 shares of common stock upon conversion of 1,739.50 shares of the Company's Series A-2 Prime Preferred Stock.

On July 25, 2024, the Company issued 375,600 shares of common stock upon conversion of 1,840.44 shares of the Company's Series A-2 Prime Preferred Stock.

On July 29, 2024, the Company issued 135,900 shares of common stock upon conversion of 665.91 shares of the Company's Series A-2 Prime Preferred Stock.

On August 14, 2024, the Company issued 350,200 shares of common stock upon conversion of 1,715.98 shares of the Company's Series A-2 Prime Preferred Stock.

On October 9, 2024, the Company issued 550,000 shares of common stock upon conversion of 2,695 shares of the Company's Series A-2 Prime Preferred Stock.

On October 31, 2024, the Company issued 43,800 shares of common stock upon conversion of 438 shares of the Company's Series B-2 Preferred Stock.

On December 11, 2024, the Company issued 462,455 shares of common stock upon conversion of 2,266.03 shares of the Company's Series A-2 Prime Preferred Stock.

On December 18, 2024, the Company issued 144,100 shares of common stock upon conversion of 1,441 shares of the Company's Series B-2 Preferred Stock.

On December 19, 2024, the Company issued 300,300 shares of common stock upon conversion of 3,003 shares of the Company's Series B-2 Preferred Stock.

On February 18, 2025, the Company issued 140,000 shares of common stock upon conversion of 686 shares of the Company's Series A-2 Prime Preferred Stock.

In June 2025, the Company issued 277,000 shares of common stock upon the exercise and conversion of Series A-3 warrants and received $1.5 million in exercise proceeds.

On June 11, 2025, the Company issued 300,000 shares of common stock upon conversion of 3,000 shares of the Company's Series B-2 Preferred Stock.

On August 26, 2025, the Company issued 652,900 shares of common stock upon conversion of 3,199.21 shares of the Company's Series A-2 Prime Preferred Stock.

Voting Rights of Common Stock

Each holder of shares of common stock shall be entitled to one vote for each share thereof held.

9. Issuance of Series A-1 Preferred Stock

On March 3, 2023, the Company issued and sold, in a private placement, 30,190 shares of Series A-1 Preferred Stock for an aggregate net proceeds of $28.0 million (the "Preferred Stock Offering"), net of placement agent fees and offering expenses of $2.2 million. The Company has used the net proceeds from the Preferred Stock Offering to support the Company's "New Drug Application" (NDA) submission for approval of oxylanthanum carbonate for the treatment of hyperphosphatemia and, if approved, for the commercial launch of oxylanthanum carbonate in the U.S.

Pursuant to the Series A Certificate of Designation, as of March 3, 2023, each share of Series A-1 Preferred Stock was, subject to approval of the Company's stockholders, convertible into a unit ("Unit") consisting of: (i) shares of common stock of the Company and, if applicable, shares of Series A-2 Preferred Stock, in lieu of common stock, (ii) a tranche A warrant to acquire approximately 4,667,594 shares (excluding deemed dividends) of Series A-3 Preferred Stock (the "Tranche A Warrant"), (iii) a tranche B warrant to acquire approximately 4,243,267 shares (excluding deemed dividends) of Series A-4 Preferred Stock (the "Tranche B Warrant"), and (iv) a tranche C warrant to acquire approximately 6,789,228 shares (excluding deemed dividends) of Series A-5 Preferred Stock (the "Tranche C Warrant", together with the Tranche A Warrant and the Tranche B Warrant, the "Warrants"). The Tranche A Warrant, for an aggregate exercise price of approximately $25 million, is exercisable until 21 days following the Company's announcement of receipt of FDA approval for oxylanthanum carbonate, the Tranche B Warrant, for an aggregate exercise price of approximately $25 million, is exercisable until 21 days following the Company's announcement of receipt of Transitional Drug Add-On Payment Adjustment ("TDAPA") approval for oxylanthanum carbonate, and the Tranche C Warrant for an aggregate exercise price of approximately $50 million is exercisable until 21 days following four quarters of commercial sales of oxylanthanum carbonate.

The Company had designated 30,190 shares of Series A-1 Preferred Stock, 1,800,000 shares of Series A-2 Preferred Stock, 1,800,000 shares of Series A-3 Preferred Stock, 1,800,000 shares of Series A-4 Preferred Stock, and 3,600,000 shares of Series A-5 Preferred Stock, together the "Series A Preferred Stock". The Series A Preferred Stock has a par value of $0.001 per share. The Series A Certificate of Designation states that, to the extent that the conversion of the Series A-1 preferred stock as well as the exercise of the Warrants into Series A-2, Series A-3, Series A-4, and Series A-5 preferred stock results in a beneficial ownership interest in excess of the maximum percentage of common stock upon conversion, the holders will receive the as converted equivalent for the remaining shares in preferred stock.

The Company determined that the Warrants are freestanding from the Series A-1 Preferred Stock, because the stock will automatically convert into shares of common stock, and the holders will be able to sell those shares while retaining the Warrants. The Company noted that at contract inception, the Warrants were contingently issuable upon the occurrence of a specified event (shareholder approval).

In connection with the Series A-1 Preferred Stock issuance, the Company recognized liabilities for the associated Warrants, which had an aggregate fair value of $2.8 million at the time of issuance. Offering costs of $0.2 million were allocated to the Warrants and expensed during March 2023. The fair value of the Warrants was accounted for as a reduction to the net proceeds of the Preferred Stock Offering, which resulted in an initial carrying value of $25.4 million for the Series A-1 Preferred Stock (net of $2.0 million of placement agent fees and offering costs allocated to the Series A-1 Preferred Stock).

On June 26, 2023, the Company held its annual shareholder meeting and, as a result, shareholder approval for the conversion of the Series A-1 Preferred Stock was obtained. On July 11, 2023, pursuant to the Series A Certificate of Designation, the Company issued 1,951,621 shares of common stock and 43,649 shares of Series A-2 Preferred Stock in partial settlement of the auto-conversion of the Series A-1 preferred shares. As of December 31, 2023, there were zero shares of Series A-1 preferred stock issued and outstanding and there were 43,649 shares of Series A-2 Preferred Stock issued and outstanding.

The Series A-2, A-3, A-4, and A-5 Preferred Stock have the following rights:

Dividends: While shares of Series A Preferred Stock are issued and outstanding, holders of Series A Preferred Stock shall be entitled to receive, and the Corporation shall pay, dividends on shares of Series A Preferred Stock equal (on an as-if-converted-to-common-stock basis) and in the same form as dividends(other than dividends in the form of common stock) actually paid on shares of the common stock when, as and if such dividends are paid on shares of the common stock.

Voting: Holders of the Series A-2, A-3, A-4, and A-5 Preferred Stock are entitled to vote together with the common stock on an as-if-converted-to-common-stock basis as determined by dividing the liquidation preference with respect to such shares of Preferred Stock by the conversion price. Holders of common stock are entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. Accordingly, holders of Series A Preferred Stock will be entitled to one vote for each whole share of common stock into which their Series A Preferred Stock is then-convertible on all matters submitted to a vote of stockholders.

At the option of the holder thereof, as of the date of the issuance of the Series A-1 Preferred on March 3, 2023, each share of Series A-2 Preferred Stock, Series A-3 Preferred Stock, Series A-4 Preferred Stock, or Series A-5 Preferred Stock shall be convertible into one share of common stock.

Exchange Agreement

On March 13, 2024, the Company entered into an exchange agreement (the "Exchange Agreement") with certain accredited investors (the "Investors"), pursuant to which the Investors surrendered all shares of Series A-2 Preferred Stock held by them in exchange for an aggregate of 21,388.01 shares of new preferred stock to be known as "Series A-2 Prime Preferred" (the "Exchanged Preferred") having rights set forth the Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock (the "Amended Series A Certificate of Designation").

Concurrent with execution of the Exchange Agreement, but prior to filing of the Amended Series A Certificate of Designation with the Delaware Secretary of State, the Company filed Certificates of Elimination for each of its Series A-1 Preferred Stock, Series A-2 Preferred Stock, Series A-3 Preferred Stock, Series A-4 Preferred Stock and Series A-5 Preferred Stock (collectively, the "Certificates of Elimination") with the Delaware Secretary of State.

Concurrent with the execution of the Exchange Agreement, the Company and each Investor have amended and restated the following warrants: (i) tranche A warrants to acquire an aggregate of 4,785,243 shares of Series A-3 Convertible Preferred Stock of the Company that were issued on July 11 2023 (the "Original Tranche A Warrants") have been amended and restated to acquire an aggregate of 2,584.03122 shares of Series A-3 Convertible Preferred Stock (as amended, the "Amended Tranche A Warrants"); (ii) tranche B warrants to acquire an aggregate of 4,350,221 shares of Series A-4 Convertible Preferred Stock of the Company that were issued on July 11, 2023 (the "Original Tranche B Warrants") have been amended and restated to acquire an aggregate of 2,566.63015 shares of Series A-4 Convertible Preferred Stock (as amended, the "Amended Tranche B Warrants") and (iii) tranche C warrants to acquire an aggregate of 6,960,353 shares of Series A-5 Convertible Preferred Stock of the Company that were issued on July 11, 2023 (the "Original Tranche C Warrants", and together with the Original Tranche A Warrants and Tranche B Warrants, the "Original Warrants") have been amended and restated to acquire 5,150.66129 shares of Series A-5 Convertible Preferred Stock (as amended, the "Amended Tranche C Warrants," together with the Amended Tranche A Warrants and the Amended Tranche B Warrants, the "Amended Warrants"). The Amended Warrants have the same terms and conditions as the original warrants except that such Amended Warrants: (i) reduced the amount of shares of Series A-3 Convertible Preferred Stock, Series A-4 Convertible Preferred Stock and Series A-5 Convertible Preferred Stock into which such Amended Warrants are convertible as described above; (ii) allow for the issuance of fractional shares of Series A-3 Preferred Stock, Series A-4 Preferred Stock and Series A-5 Preferred Stock, as applicable upon exercise of such Amended Warrants and (ii) revised the exercise price to be $1,000 per share of Series A-3 Preferred Stock, Series A-4 Preferred Stock and Series A-5 Preferred Stock, as applicable in such Amended Warrants. The aggregate exercise price, the amount of shares of common stock upon conversion of the Series A-3 Preferred Stock, the Series A-4 Preferred Stock and the Series A-5 Preferred Stock and exercise period in the Amended Warrants did not change from the Original Warrants.

Pursuant to the terms of the Exchange Agreement, effective March 13, 2024, the Company filed the Amended Certificate of Designation with the Delaware Secretary of State designating, 21,400 shares as Series A-2 Prime Preferred Stock, 25,900 shares as Series A-3 Convertible Preferred Stock, 25,700 shares as Series A-4 Convertible Preferred Stock, and 51,600 shares as Series A-5 Convertible Preferred Stock (all such series of preferred stock referred to herein collectively as "Series A Preferred Stock"), each with a stated value of $1,000 per share (the "Original Per Share Price"). The Amended Certificate of Designation sets forth the rights, preferences and limitations of the shares of Series A Preferred Stock. Terms not otherwise defined in this item shall have the meanings given in the Amended Certificate of Designation. The Amended Certificate of Designation was filed with an effective date of March 14, 2024 and the Series A-2 Prime, A-3, A-4, and A-5 Preferred Stock have the following rights, has the following terms:

Dividends. At all times following the Issuance Date, while shares of Series A Preferred Stock are issued and outstanding, holders of Series A Preferred Stock shall be entitled to receive, and the Company shall pay, dividends on shares of Series A Preferred Stock equal (on an as-if-converted-to-common-stock basis and without regard to any limitations on conversion set forth herein or otherwise) to and in the same form as dividends (other than dividends in the form of common stock, which shall be made in accordance with the terms of the Amended Certificate of Designation) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock, which shall be made in accordance with the terms of the Amended Certificate of Designation) are paid on shares of the common stock.

Voting Rights. Subject to certain limitations described in the Amended Certificate of Designation, the Series A Preferred Stock is voting stock. Holders of the Series A Preferred Stock are entitled to vote together with the common stock on an as-if-converted-to-common-stock basis. Holders of common stock are entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. Accordingly, holders of Series A Preferred Stock will be entitled to one vote for each whole share of common stock into which their Series A Preferred Stock is then-convertible on all matters submitted to a vote of stockholders.

Liquidation. Upon any Liquidation, the assets of the Company available for distribution to its stockholders shall be distributed among the holders of the shares of Series A Preferred Stock and common stock, pro rata based on the number of shares held by each such holder, treating for this purpose all shares of Series A Preferred Stock as if they had been converted to common stock pursuant to the terms of the Amended Certificate of Designation immediately prior to such Liquidation, without regard to any limitations on conversion set forth in the Amended Certificate of Designation or otherwise.

Conversion. Subject to the limitations set forth in the Amended Certificate of Designation, at the option of the holder, each share of Series A-2 Prime Preferred Stock, Series A-3 Convertible Preferred Stock, Series A-4 Convertible Preferred Stock or Series A-5 Convertible Preferred Stock shall be convertible into a number shares of common stock obtained by dividing the Original Per Share Price ($1,000) of each such share of Series A-2 Prime Convertible Preferred Stock, Series A-3 Convertible Preferred Stock, Series A-4 Convertible Preferred Stock or Series A-5 Convertible Preferred Stock by the applicable conversion price of $4.90, $0.54, $0.59 and $0.74 for the Series A-2 Prime Convertible Preferred Stock, Series A-3 Convertible Preferred Stock, Series A-4 Convertible Preferred Stock or Series A-5 Convertible Preferred Stock, respectively. Pursuant to the terms of the Certificate of Correction to the Amended Series A Certificate of Designation filed on August 13, 2025 (which correction was effective as of March 14, 2024 pursuant to Section 103(f) of the Delaware General Corporation Law), there was no adjustment to the conversion prices for the Series A-3, A-4 and A-5 Preferred Stock as there were no shares outstanding in such series of preferred stock at the time of the reverse stock split. As of December 31, 2025, there were 2,265 shares of Series A-2 Prime Preferred Stock outstanding.

10. Issuance of Series B-1 Preferred Stock and Series B-2 Preferred Stock

On March 13, 2024, the Company signed a securities purchase agreement with certain healthcare-focused institutional investors that provided $50.0 million in gross proceeds through a private placement. Pursuant to the securities purchase agreement, the Company issued to institutional investors $50.0 million in shares of Series B-1 Convertible Preferred Stock. 50,000 Shares of Series B-1 Convertible Preferred Stock were issued at a price of $1,000 per share and each share is convertible into shares of common stock at a rate equal to the initial $1,000 purchase price divided by the initial conversion price of $1.00 per share.

Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series B Convertible Preferred Stock filed with the Delaware Secretary of State on March 14, 2024, as corrected by the Certificate of Correction to Series B Certificate of Designation filed with the Delaware Secretary of State on November 8, 2024 (the "Series B Certificate of Designation"), each share of Series B-1 Preferred Stock is, subject to approval of the Company's stockholders, convertible into shares of common stock of the Company and, if applicable, shares of Series B-2 Convertible Preferred Stock (the "Series B-2 Preferred Stock"), in lieu of common stock.

The Company has designated 50,000 shares of Series B-1 Preferred Stock and 50,000 shares of Series B-2 Preferred Stock. The Series B Certificate of Designation states that, to the extent that the conversion of the Series B-1 preferred stock results in a beneficial ownership interest in excess of the maximum percentage of common stock upon conversion, the holders will receive them as converted equivalent for the remaining shares in preferred stock.

On June 20, 2024, The Company held its annual stockholder meeting, and as a result, stockholder approval for the conversion of the Series B-1 Convertible Preferred Stock was obtained ("Stockholder Approval"). On July 5, 2024, pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series B Convertible Preferred Stock, the Company issued 4,211,800 shares of common stock and 7,882 shares of Series B-2 preferred stock in settlement of the automatic conversion of the Series B-1 Convertible Preferred Stock.

The Series B-1 Preferred Stock had the following rights:

Dividends: Prior to receiving Stockholder Approval, dividends accrued, on all issued and outstanding shares of Series B-1 Preferred Stock, prior to and in preference to all other shares of capital stock of the Company, at an annual rate of eight percent (8%) compounded annually on the original per share price (plus any such accreted compounded amounts); provided that such annual dividend rate shall increase to fourteen percent (14%) if Stockholder Approval is not obtained at the first meeting of stockholders following the date of the Preferred Stock offering. If such dividends are not declared and paid in cash, the dividend amounts will be added to the aggregate liquidation preference then outstanding of the Series B-1 Preferred Stock.

At all times following the Issuance Date, while shares of Series B-1 Preferred Stock are issued and outstanding, holders of Series B Preferred Stock shall be entitled to receive, and the Company shall pay, dividends on shares of Series B-1 Preferred Stock equal (on an as-if-converted-to-Common-Stock basis and without regard to any limitations on conversion set forth herein or otherwise) to and in the same form as dividends (other than dividends in the form of common stock, which shall be made in accordance with the terms of the Series B Certificate of Designation) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock, which shall be made in accordance with the terms of the Series B Certificate of Designation) are paid on shares of the common stock. Stockholder approval was received on June 20, 2024.

Voting: Subject to certain limitations described in the Series B Certificate of Designation holders of the Series B-1 Preferred Stock are entitled to vote together with the common stock on an as-if-converted-to-common-stock basis as determined by dividing the liquidation preference with respect to such shares of Series B-1 Preferred Stock by the conversion price. Holders of common stock are entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. Unless and until the Company has obtained the Stockholder Approval, the number of shares of common stock that shall be deemed issued upon conversion of the Series B Preferred Stock (for purposes of calculating the number of aggregate votes that the holders of Series B Preferred Stock are entitled to on an as-converted basis) will be equal to that number of shares equal to 19.9% of the Company's outstanding common stock as of the Signing Date (excluding for purposes of the calculation, any securities issued on the Signing Date) (the "Cap"), which each such holder being able to vote the number of shares of Series B Preferred Stock held by it relative to the total number of shares of Series B Preferred Stock then outstanding multiplied by the Cap. Notwithstanding the foregoing, the holders of the Series B Preferred Stock are not entitled to vote together with the common stock on an as-if-converted-to-Common-Stock-basis with regard to the approval of the issuance of common stock upon conversion of the Series B Preferred Stock.

On the tenth trading day following the announcement of the Stockholder Approval, each share of Series B-1 Preferred Stock automatically converted into a unit consisting of: (1) the number of shares of common stock equal to the quotient of (A) the liquidation preference with respect to such share of Series B-1 Preferred Stock, divided by (B) the conversion price, provided that, to the extent the share conversion would cause such Holder's beneficial ownership to exceed 9.99%, such holder shall receive shares of Series B-2 Preferred Stock in lieu of common stock, on a one-for-one basis, with respect to the number of shares of common stock that exceed 9.99% ownership divided by 1,000.

Liquidation Preference: The Series B-1 Preferred Stock had a liquidation preference of one-times the original per share price of $1,000 per share, plus any accrued but unpaid dividends thereon, whether or not declared, subject to certain customary anti-dilution adjustments.

The Series B-2 Preferred Stock has the following rights:

Dividends: Following the Issuance Date, while shares of Series B Preferred Stock are issued and outstanding, holders of Series B Preferred Stock shall be entitled to receive, and the Corporation shall pay, dividends on shares of Series B Preferred Stock equal (on an as-if-converted-to-common-stock basis and without regard to any limitations on conversion set forth herein or otherwise) to and in the same form as dividends (other than dividends in the form of common stock, which shall be made in accordance with Section 7(a)) actually paid on shares of the common stock when, as and if such dividends (other than dividends in the form of common stock, which shall be made in accordance with Section 7(a)) are paid on shares of the common stock.

Voting: Subject to certain limitations described in the Series B Certificate of Designation, the Series B-2 Preferred Stock is voting stock. Holders of the SeriesB-2 Preferred Stock are entitled to vote together with the common stock on an as-if-converted-to-common-stock basis. Holders of common stock are entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders. Accordingly, holders of Series B-2 Preferred Stock will be entitled to one vote for each whole share of common stock into which their Series B-2 Preferred Stock is then-convertible on all matters submitted to a vote of stockholders.

Liquidation: Upon any Liquidation, the assets of the Company available for distribution to its stockholders shall be distributed among the holders of the shares of Series B Preferred Stock and common stock, pro rata based on the number of shares held by each such holder, treating for this purpose all shares of Series B preferred Stock as if they had been converted to common stock pursuant to the terms of the Certificate of Designation immediately prior to such Liquidation, without regard to any limitations on conversion set forth in the Series B Certificate of Designation or otherwise.

Conversion: Subject to the limitations set forth in the Series B Certificate of Designation, at the option of the holder thereof, each share of Series B-2 Preferred Stock, is convertible into the number of shares of common stock equal to the quotient of (A) the stated value ($1,000), divided by (B) the conversion price of $10.00. As of December 31, 2025, all shares of Series B-2 Preferred Stock have been converted into common stock.

11. Warrant Liability

In connection with the Series A Preferred Stock Offering (see Note 9), the Company issued the Warrants.

After the Warrants were legally issued as a result of the automatic conversion of the Series A-1 Preferred Stock upon shareholder approval, they became immediately exercisable at the option of the holder. The Company determined that the Warrants, while initially contingently issuable, qualified as derivative instruments pursuant to ASC 815-40, *Contracts in an Entity's Own Equity* and that the Warrants were considered issued for accounting purposes concurrently with the Series A-1 Preferred Stock.

On June 26, 2023, the Company held its annual shareholder meeting, and as a result, shareholder approval for the conversion of the Series A-1 Preferred Stock was obtained. On July 11, 2023, pursuant to the Series A Certificate of Designation, the Company issued, in addition to common stock and Series A-2 Preferred Stock, (i) a Tranche A Warrant to acquire 4,785,243 shares of Series A-3 Preferred Stock, (ii) a Tranche B Warrant to acquire 4,350,221 shares of Series A-4 Preferred Stock, and (iii) a Tranche C Warrant to acquire 6,960,353 shares of Series A-5 Preferred Stock.

In March 2024, the Company entered into an exchange agreement with certain accredited investors, pursuant to which the accredited investors surrendered all shares of Series A-2 Preferred Stock held by them in exchange for shares of new preferred stock to be known as Series A-2 Prime Preferred Stock having rights set forth in the Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock.

The Warrants are recognized as liabilities in the balance sheets and were initially recognized at fair value at the time of issuance. The Warrants are also subject to remeasurement at each balance sheet date after issuance. Any change in fair value is recognized as a component of other income (expenses) in the statements of operations in the period of change.

The valuation of the Warrants contains unobservable inputs that reflect the Company's own assumptions for which there is little market data. Accordingly, the Warrants are measured at fair value on a recurring basis using unobservable inputs and are classified as Level 3 inputs. The significant unobservable inputs used in the fair value measurement of the Company's Warrants include, but are not limited to, probability of obtaining certain shareholder approvals, probability of reaching certain technical milestones related to the development of oxylanthanum carbonate, and the estimated term of the Warrants. Significant increases (decreases) in any of those inputs in isolation would result in a significantly higher (lower) fair value measurement. Generally, a change in the assumption used for the probability of obtaining certain shareholder approvals is not correlated to a change in the probability of reaching certain technical milestones. However, a change to the assumption used for the probability of obtaining certain shareholder approvals or a change in the probability of reaching certain technical milestones would have been accompanied by a directionally opposite change and a directionally similar change, respectively, in the assumption used for the estimated term.

The fair value of the Warrants associated with the Company's March 2023 private placement transaction was determined as of March 3, 2023, and March 31, 2023, by using a Monte Carlo simulation technique ("MCS") to value the embedded derivatives associated with the Warrants. The MCS methodology calculates the theoretical value of a warrant based on certain parameters, including: (i) the threshold of exercising the warrant, (ii) the price of the underlying security, (iii) the time to expiration, or expected term, (iv) the expected volatility of the underlying security, (v) the risk-free rate, (vi) the number of paths, (vii) estimated probability assumptions surrounding shareholder approval as well as the achievement by the Company of technical milestones associated with regulatory and commercial progress, and (viii) an estimated discount for lack of marketability.

The MCS valuation model was used for the valuation performed as of the transaction inception on March 3, 2023, and on March 31, 2023, due to uncertainty in the timing of shareholder approval and the potential variability in the Warrant exercise price. On June 26, 2023, the Company held its annual shareholder meeting, and as a result, shareholder approval for the issuance of common shares upon the conversion of the Series A-1 Preferred Stock was obtained and the exercise price for the Warrants became fixed. Therefore, as of December 31, 2024 and December 31, 2025, the fair value of the Warrants was determined using a Black Scholes model using parameters including (i) the exercise price of the warrant, (ii) the price of the underlying security, (iii) the time to expiration, or expected term, (iv) the expected volatility of the underlying security, (v) the risk-free rate, (vi) discount for lack of marketability, and (vii) estimated probability assumptions surrounding the achievement by the Company of technical milestones associated with regulatory and commercial progress.

These valuation techniques involve management's estimates and judgment based on unobservable inputs and are classified in Level 3. The fair value estimates may not be indicative of the amounts that would be realized in a market exchange. Additionally, there may be inherent uncertainties or changes in the underlying assumptions used, which could significantly affect the current or future fair value estimates. Generally, a significant increase (decrease) in the probabilities of shareholder approval and the achievement of technical milestones would have resulted in a significantly higher (lower) fair value measurement; however, changes in other inputs such as expected term and price of the underlying common stock will have a directionally opposite impact on fair value measurement.

The Company uses a third-party valuation expert to assist in the determination of the fair value of the Warrants. The tables below summarize the valuation inputs into the Black Scholes model for the liability associated with the three tranches of Warrants at December 31, 2024 and December 31, 2025.

Tranche A Warrant	**At December 31, 2024**	**At December 31, 2025**
Fair value of underlying stock	$ 7.90	$ 5.77
Exercise price	$ 5.39	$ 5.39
Volatility	105.4% – 111.3%	61.6% – 100.3%
Risk free rate	4.2%	3.5% – 3.7%
Dividend yield	0%	0%
Term (in years)	0.5 – 1.5	0.2 – 1.0
Discount for lack of marketability	7.5%	5.0%
Probability for receipt of FDA approval for oxylanthanum carbonate	38.48% - 39.29%	64.80% - 66.83%

Tranche B Warrant	**At December 31, 2024**	**At December 31, 2025**
Fair value of underlying stock	$ 7.90	$ 5.77
Exercise price	$ 5.93	$ 5.93
Volatility	105.4% – 125.2%	100.3% - 108.2%
Risk free rate	4.2%	3.5%
Dividend yield	0%	0%
Term (in years)	1.0 – 2.0	0.7 - 1.5
Discount for lack of marketability	7.5%	5%
Probability for receipt of Transitional Drug Add-On Payment Adjustment approval for oxylanthanum carbonate	30%	70.0%

Tranche C Warrant	At December 31, 2024	At December 31, 2025
Fair value of underlying stock	$ 7.90	$ 5.77
Exercise price	$ 7.41	$ 7.41
Volatility	105.4% – 125.2%	99.0% - 105.0%
Risk free rate	4.2%	3.5%
Dividend yield	0%	0%
Term (in years)	1.5 – 2.5	1.2 – 2.0
Discount for lack of marketability	7.5%	5%
Probability for public disclosure of financial results for four (4) quarters of commercial sales for oxylanthanum carbonate following receipt of Transitional Drug Add-On Payment Adjustment approval	0.01% - 27.46%	1.56% - 51.2%

As of the issuance date (March 3, 2023), the Company estimated the fair value of the Warrants to be $2.8 million. As of December 31, 2024 and December 31, 2025, the Company estimated the fair value of the Warrants to be $18.9 million and $16.9 million, respectively.

The following table summarizes activity, on an as-converted to common shares basis, for the Company's preferred stock warrants for the year ended December 31, 2025:

	Number of Shares Underlying Outstanding Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2024	16,095,817	$ 6.40	2.12	$ -
Warrants contingently issuable	-	-	-	-
Warrants exercised	(277,000)	-	-	-
Outstanding, December 31, 2025	15,818,817	$ 6.41	1.12	$ -

12. Stock-based Compensation

On July 15, 2021, in connection with the completion of the Company's IPO, the Company adopted a new comprehensive equity incentive plan, the 2021 Omnibus Equity Incentive Plan (the "2021 Plan"). Following the effective date of the 2021 Plan, no further awards may be issued under the 2018 Plan or the 2019 Plan (collectively, the "Prior Plans"). However, all awards under the Prior Plans that are outstanding as of the effective date of the 2021 Plan will continue to be governed by the terms, conditions and procedures set forth in the Prior Plans and any applicable award agreements. A total of 130,233 shares of common stock were reserved for issuance pursuant to the 2021 Plan prior to our annual meeting on June 26, 2023. Shareholders approved an increase to the number of shares reserved on June 26, 2023, and accordingly, at December 31, 2023, approximately 1,277,600 shares were reserved for issuance. On June 20, 2024, shareholders approved a further increase of 800,000 shares, to the number of shares reserved, for a total of 2,077,600 shares. On January 1, 2025, pursuant to a 4% evergreen increase provision in the 2021 Plan, the amount of shares reserved under the Plan increased by 1,235,316 shares, to the number of shares reserved, for a total of 3,312,916 shares. The 2021 Plan provides for the issuance of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards. As of December 31, 2024, approximately 743,333 shares of common stock were available under the 2021 Plan. As of December 31, 2025, there are approximately 1,310,150 shares of common stock available under the 2021 Plan. On January 1, 2026, pursuant to a 4% evergreen increase provision in the 2021 Plan, the amount of shares reserved under the Plan increased by 884,570 shares, to the number of shares reserved, for a total of 4,197,486 shares.

The following table summarizes activity for stock options under all plans for the year ended December 31, 2025:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2024	1,367,114	$ 10.01	8.59	$ 705
Options granted	669,500	$ 4.81	9.56	$ -
Options forfeited	(3,500)	$ 5.70	-	$ -
Options exercised	-	$ -	-	$ -
Outstanding, December 31, 2025	2,033,114	$ 8.31	8.23	$ 10,347
Options vested and exercisable as of December 31, 2025	896,043	$ 10.79	7.13	$ 4,219

The grant date fair value of options granted during the year ended December 31, 2025, was approximately $2.8 million.

As of December 31, 2025, the unrecognized compensation cost related to outstanding stock options was $5.6 million, which is expected to be recognized as expense over approximately 3.6 years.

During the year ended December 31, 2021, employees and consultants exercised a total of 38,372 stock options and the Company received $119,000 in proceeds. A portion of these options were exercised early (prior to vesting), and as of December 31, 2024, none of the options remained unvested. Proceeds received related to the vested portion of options of $2,500 were reclassified to equity during the year ended December 31, 2024.

During May 2022, the Company granted a consultant 1,000 restricted stock units with a grant date fair value of $7,200, resulting in a fair value per share of $7.20. The restricted stock units vested in May 2024.

During August 2023, the Company granted a consultant 1,000 restricted stock units with a grant date fair value of $7,500, resulting in a fair value per share of $7.50. The restricted stock units vested in March 2025.

During August 2024, the Company granted a consultant 1,177 restricted stock units with a grant date fair value of $4,000, resulting in a fair value per share of $3.40. The restricted stock units will vest in August 2026.

During July 2025, the Company granted a consultant 2,500 restricted stock units with a grant date fair value of $11,775, resulting in a fair value per share of $4.71. The restricted stock units will vest in July 2027.

The Company has recorded stock-based compensation expense, which includes expense related to restricted stock units, allocated by functional cost as follows for the years ended December 31, 2024 and 2025 (in thousands):

	Year Ended December 31, 2024	Year Ended December 31, 2025
Research and development	$ 1,058	$ 1,201
General and administrative	1,292	1,440
Total stock-based compensation	$ 2,350	$ 2,641

Fair Value of Stock Options

The assumptions are based on the following for each of the periods presented:

Expected Term - The expected term is calculated using the simplified method which is used when there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method.

Common Stock Fair Value - The fair value of the common stock underlying the Company's stock options prior to the initial public offering was estimated at each grant date and was determined on a periodic basis and based either on transactions with third parties in which common stock was sold for cash or with the assistance of an independent third-party valuation expert. Subsequent to our initial public offering, the fair value underlying the Company's common stock is determined based on the public market closing price on each date of grant. The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of significant levels of management judgment.

Volatility - The expected volatility being used is derived from the historical stock volatilities of a representative industry peer group of comparable publicly listed companies over a period approximately equal to the expected term of the options.

Risk-free Interest Rate - The risk-free interest rate is based on median U.S. Treasury zero coupon issues with remaining terms similar to the expected term on the options.

Expected Dividend – Through December 31, 2025, the Company has never declared nor paid any cash dividends on common stock. The Company shall modify its dividend policy to state that the Company intends to pay dividends to all stockholders, including holders of Series A Preferred Stock on an as-if-converted-to-common-stock basis, on a quarterly basis in an amount of which the aggregate of all quarterly dividends shall equal at least seventy-five percent (75%) of its annual net cash flow from operations following the approval of oxylanthanum carbonate by the FDA if obtained, and the commencement of commercial sales.

The following averaged assumptions were used to calculate the fair value of awards granted to employees, directors and non-employees for the years ended December 31, 2024 and December 31, 2025:

	Year Ended December 31, 2024	Year Ended December 31, 2025
Expected volatility	105%-107%	107.44% - 116.54%
Risk-free interest rate	3.78% - 4.65%	3.75% - 4.38%
Dividend yield	-%	-%
Expected term	6.25 years	5.50 years - 6.25 years

13. Income Taxes

The Company's pre-tax loss for the years ended December 31, 2024 and 2025 is from U.S. operations. For the years ended December 31, 2024 and 2025, the Company did not record a current or deferred income tax expense or benefit.

A reconciliation of the provision for income taxes to the amount computed by applying the statutory income tax rate of 21% to the net loss is summarized for the year ended December 31, 2024 as follows:

	Year Ended December 31, 2024
Income taxes (benefit) at statutory rates	21.00%
State income tax (benefit), net of federal benefit	5.84%
Change in valuation allowance	(23.12)%
Fair value adjustment on warrants	(3.32)%
Officers' compensation	(1.05)%
Other	0.65%
Effective income tax rate	0.00%

The table below provides the updated requirements of ASU 2023-09 (in thousands) for the year ended December 31, 2025:

	Year Ended December 31, 2025	
	Amount	Percentage
Provision for income taxes at U.S. federal statutory rate	$ (5,576)	21.00%
State and local income taxes, net of federal benefit (1)	(178)	0.67%
Tax Credits		
Research and development ("R&D") credits	(458)	1.72%
Changes in valuation allowance	5,599	(21.09)%
Non-taxable or non-deductible items:		
Officers' compensation	279	(1.05)%
Fair value adjustment on warrants	(424)	1.60%
Other	122	(0.45)%
Changes in unrecognized tax benefits	636	(2.40)%
Other adjustments:		
Other	-	0.00%
	$ -	0.00%

(1) The state(s) that contribute to the majority (greater than 50%) of the tax effect in this category is California for year ending December 31, 2025.

The Company did not pay federal or state cash income taxes or have cash income taxes refunded in the year ended December 31, 2025.

Deferred tax assets and liabilities are recognized for the expected tax consequences attributable to the differences between financial reporting and the tax basis of existing assets and liabilities and operating loss carryforward, and they are measured using enacted tax rates expected to be in effect when differences are expected to reverse. A valuation allowance is recorded for loss carryforwards and other deferred tax assets where it is more likely than not that such loss carryforward and deferred tax asset will not be realized. Significant components of the Company's deferred tax assets at December 31, 2024 and 2025 are shown below (in thousands):

	December 31, 2024	December 31, 2025
Deferred tax assets:		
Stock-based compensation	$ 730	$ 1,041
Net operating losses carryforwards	11,022	16,651
Depreciation and amortization	960	915
Capitalized research	6,572	7,023
Accrued expenses	553	30
Other	-	37
Total gross deferred tax assets	19,837	25,697
Less: valuation allowance	(19,668)	(25,669)
Net deferred tax assets, net of valuation allowance	$ 169	$ 28
Deferred tax liabilities:		
Other	$ (169)	$ (28)
Total deferred tax liabilities	(169)	(28)
Net deferred tax assets / liabilities	$ -	$ -

The valuation allowance increased by $6 million during the year ended December 31, 2025. The Company has concluded, based upon ASC 740, that it is more likely than not the Company will not realize any benefit from the deferred tax assets related to certain Federal and state net operating loss and credit carryforwards. Accordingly, the Company has established a full valuation allowance against its Federal and state deferred tax assets.

As of December 31, 2025, the Company had available Federal and state net operating loss carryforwards of approximately $64 million and $46.8 million, respectively, to reduce future taxable income, if any. Federal net operating losses generated prior to 2018 and all state net operating losses generated expire in varying amounts beginning in 2037. The net operating losses generated after 2017 do not expire and will be able to offset 80% of taxable income generated in the future.

As of December 31, 2025, the Company had research and development credit carryforwards of approximately $1.8 million and $0.9 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. These credits are fully reserved against under ASC 740-10. The federal credit carryforwards begin to expire in 2037, and the state credit carryforwards can be carried forward indefinitely.

Utilization of net operating losses and tax credits may be subject to an annual limitation due to ownership change limitations provided in the Internal Revenue Code of 1986, as amended (the "Code"), and similar state provisions. The effect of an ownership change would be the imposition of annual limitation on the use of net operating loss ("NOL") carryforwards attributable to periods before the change in ownership. An assessment of such ownership changes under Section 382 of the Code was not completed through December 31, 2025, and as such the Company is not able to determine the impact on the NOLs and tax credit carryforwards, if any, as of the date of the financial statements. To the extent that an assessment is completed in the future, the Company's ability to utilize tax attributes could be restricted on a year-by-year basis and certain attributes could expire before they are utilized.

The Company applies the guidance under ASC 740, subtopic 10-50-15, Unrecognized Tax Benefit Related Disclosures (formerly FASB Interpretation 48, Accounting for Uncertainty in Income Taxes). For benefits to be realized, a tax position must be more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50% likely of being realized upon settlement. This interpretation also provides guidance on measurement, de-recognition, classification, interest and penalties.

The following table summarizes the changes to the Company's gross unrecognized tax benefits for the years ended December 31, 2024 and 2025 (in thousands):

	Year Ended December 31, 2024	Year Ended December 31, 2025
Beginning balance	$ 1,027	$ 1,985
Additions related to current year positions	958	649
Additions related to prior year positions	-	34
Ending balance	$ 1,985	$ 2,668

As of December 31, 2024 and 2025, the total unrecognized tax benefit was approximately $2 million and $2.7 million, respectively. The Company's policy is to recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2025, the Company had no accrued interest and penalties related to uncertain tax positions.

The Company files U.S. federal and state income tax returns with varying statutes of limitations. Tax years 2018 and forward remain open to examination due to the carryover of NOL carryforwards. There are no ongoing examinations by taxing authorities at this time.

On July 4, 2025, the U.S. President signed into law H.R.1, the legislation commonly known as the One Big Beautiful Bill Act (OBBBA). This legislation extended, modified, or made permanent many of the tax provisions which were initially enacted as part of the Tax Cuts and Jobs Act (TCJA) of 2017. The OBBBA contains a number of tax provisions including, but not limited to, immediate expensing of domestic research and experimental expenditures, modifications to the limitation on business interest, bonus depreciation modifications, as well as international tax provision modifications. These tax provisions apply to either tax years beginning after December 31, 2024 or December 31, 2025. The impact of this legislation was not material to the Company's financial position and results of operation for the year ended December 31, 2025.

Income Taxes Disclosures – In December 2023, the FASB issued ASU No. 2023-09, "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." ASU2023-09 requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. ASU 2023-09 is effective for public entities with annual periods beginning after December 15, 2024, with early adoption permitted. The Company adopted this standard prospectively for the period ending December 31, 2025. The adoption of the standard impacted the 2025 income tax disclosures.

14. Net Loss Per Share

The Company computes net income (loss) per share using the two-class method. The two-class method uses an earnings allocation formula that determines net income (loss) per share for common stock and any participating securities according to dividends declared and participation rights in undistributed earnings.

Diluted net income (loss) per share includes the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock units; (ii) common stock to be issued upon the assumed exercise of the Company's common stock warrants; (iii) convertible preferred stock; and (iv) prior to issuance, the issuable warrants related to the Company's March 2023 private placement financing.

The following table sets forth the computation of basic and diluted net loss per share of common and preferred stock (in thousands, except share and per share data):

	Year Ended December 31, 2024	Year Ended December 31, 2025
Basic net loss per share		
Numerator:		
Net loss	$ (36,729)	$ (26,555)
Cash Dividends to Series B holders	(1,095)	-
Net loss attributable to common shares, basic and diluted	(37,824)	(26,555)
Denominator:		
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	6,698,513	15,886,876
Net loss per share attributable to common stockholders, basic and diluted	$ (5.65)	$ (1.67)

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	Year Ended December 31, 2024	Year Ended December 31 2025
Options to purchase common stock	1,367,114	2,033,114
Warrants to purchase common stock	478,419	478,419
Restricted stock units	2,177	3,677
Common stock issuable upon conversion of Series B-2 convertible preferred stock	300,000	-
Common stock issuable upon conversion of Series A-2 Prime convertible preferred stock	1,255,145	462,245
Warrants to purchase convertible preferred stock	16,095,817	15,818,817
Total	19,498,672	18,796,272

15. Subsequent Events

Subsequent to December 31, 2025, pursuant to a sales agreement dated November 13, 2024 between the Company and Guggenheim Securities, LLC, as amended by Amendment No. 1 thereto dated November 14, 2025, the Company sold 3,123,537 shares of common stock at an average price of $6.51 per share, resulting in net proceeds to the Company of approximately $19.6 million.

On March 12, 2026, a purported stockholder made a demand on the Company's Board of Directors to commence a civil action against certain of the Company's current and former officers and directors for breaching their fiduciary duties based on the same alleged misconduct as alleged in the Securities Class Action and Derivative Actions described in Note 7 (the "Demand"). At this early stage of the proceedings, the Company is unable to make any prediction regarding the outcome of the Securities Class Action, the Derivative Actions, or the Demand.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls

Our principal executive officer and principal financial officer evaluated the effectiveness of our "disclosure controls and procedures" as of December 31, 2025, the end of the period covered by this Annual Report on Form 10-K. The term "disclosure controls and procedures" as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files under the Exchange Act is accumulated and communicated to a company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Based on the evaluation of our disclosure controls and procedures as of December 31, 2025, our Chief Executive Officer and our Chief Financial Officer determined that we maintained effective internal control over financial reporting as of December 31, 2025.

Management Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of December 31, 2025, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework - 2013. Based on this assessment, our management concluded that, as of December 31, 2025, our internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to the exemption provided to issuers that are not "large accelerated filers" nor "accelerated filers" under the Dodd-Frank Wall Street Reform and Consumer Protection Act.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with the evaluation that occurred during the quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, the internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference from the information contained in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of Stockholders to be held in 2026 (the "2026 Proxy Statement"), under the heading "Election of Directors."

We have adopted a code of business conduct and ethics that applies to all our employees, officers and directors, including those officers responsible for financial reporting. Our code of business conduct and ethics is available on the investors section of our website. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Conduct by posting such information on the website address and location specified above.

We have adopted an insider trading policy applicable to our directors, officers, employees, and other covered persons, and have implemented processes for the company, that we believe are reasonably designed to promote compliance with insider trading laws, rules and regulations, and the Nasdaq Capital Market listing standards. Our insider trading policy is included as Exhibit 19.1 to this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement under the heading "Executive Compensation."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement under the heading "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement under the heading "Certain Transactions."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference from the information contained in the 2026 Proxy Statement under the heading "Proposal 2: Ratification of the Appointment of Our Independent Registered Public Accounting Firm for Fiscal Year Ending December 31, 2026."

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) Financial Statements:

The financial statements required by this Item are included beginning at page F-1.

(2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(b) Exhibits

The following documents are included as exhibits to this report.

Exhibit No.	Description
1.1	Sales Agreement, dated as of November 13, 2024, between the Company and Guggenheim Securities, LLC (incorporated by reference to Exhibit 1.1 of Form S-3 filed on November 13, 2024)
1.2	Amendment No. 1 to Sales Agreement, dated November 14, 2025, between Unicycive Therapeutics, Inc. and Guggenheim Securities, LLC (incorporated by reference to Exhibit 1.1 to Form 8-K filed on November 14, 2025)
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.4 to Amendment No. 2 to Form S-1 filed on June 21, 2021)
3.2	Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on March 6, 2023)
3.3	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.5 to Amendment No. 2 to Form S-1 filed on June 21, 2021)
3.4	Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock (incorporated by reference to Exhibit 3.6 to Form 8-K filed on March 14, 2024)
3.5	Certificate of Elimination of Series A-1 Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on March 14, 2024)
3.6	Certificate of Elimination of Series A-2 Preferred Stock (incorporated by reference to Exhibit 3.2 to Form 8-K filed on March 14, 2024)
3.7	Certificate of Elimination of Series A-3 Preferred Stock (incorporated by reference to Exhibit 3.3 to Form 8-K filed on March 14, 2024)
3.8	Certificate of Elimination of Series A-4 Preferred Stock (incorporated by reference to Exhibit 3.4 to Form 8-K filed on March 14, 2024)
3.9	Certificate of Elimination of Series A-5 Preferred Stock (incorporated by reference to Exhibit 3.5 to Form 8-K filed on March 14, 2024)
3.10	Certificate of Designation of Preferences, Rights and Limitations of the Series B Convertible Voting Preferred Stock (incorporated by reference to Exhibit 3.1 to Form 8-K filed on March 14, 2024)
3.11	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Form 8-K filed on June 26, 2024).
3.12	Certificate of Correction to Series B Preferred Certificate of Designation filed with the Delaware Secretary of State on November 8, 2024, incorporated by reference to Exhibit 3.1 to Form 10-Q for the period ended September 30, 2024 filed on November 13, 2024
3.13	Certificate of Amendment to the Amended and Restated Certificate of Incorporation, as amended, dated June 18, 2025, (incorporated by reference to Exhibit 3.1 to Form 8-K filed on June 20, 2025)
3.14	Certificate of Correction to Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Voting Preferred Stock filed with the Delaware Secretary of State on August 13, 2025, (incorporated by reference to Exhibit 3.1 to Form 10-Q for the period ended June 30, 2025 filed on August 14, 2025)
4.1	Specimen Stock Certificate evidencing the shares of common stock (incorporated by reference to Exhibit 4.1 to Form S-1 filed on May 21, 2021)
4.2	Form of Warrant Agent Agreement (including the terms of the Warrant) (incorporated by reference to Exhibit 4.2 to Amendment No. 2 to Form S-1 filed on June 21, 2021)
4.3	Form of Underwriter's Unit Purchase Option (incorporated by reference to Exhibit 4.3 to Amendment No. 2 to Form S-1 filed on June 21, 2021)
4.4*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934
4.5	Form of Specimen Stock Certificate for Series A-1 Preferred Stock (incorporated by reference to Exhibit 4.1 to Form 8-K filed on March 6, 2023)
4.6	Form of Tranche A Warrant (incorporated by reference to Exhibit 4.2 to Form 8-K filed on March 6, 2023)
4.7	Form of Tranche B Warrant (incorporated by reference to Exhibit 4.3 to Form 8-K filed on March 6, 2023)
4.8	Form of Tranche C Warrant (incorporated by reference to Exhibit 4.4 to Form 8-K filed on March 6, 2023)
4.9	Form of Amended and Restated Tranche A Warrant (incorporated by reference to Exhibit 4.1 to Form 8-K filed on March 14, 2024)
4.10	Form of Amended and Restated Tranche B Warrant (incorporated by reference to Exhibit 4.2 to Form 8-K/A filed on April 14, 2025)
4.11	Form of Amended and Restated Tranche C Warrant (incorporated by reference to Exhibit 4.3 to Form 8-K/A filed on April 14, 2025)
10.1+	2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to Form S-1 filed on June 7, 2021)
10.2+	2019 Stock Option Plan (incorporated by reference to Exhibit 10.2 to Amendment No. 1 to Form S-1 filed on June 7, 2021)
10.3+	2021 Omnibus Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to Form S-1 filed on June 7, 2021)
10.4	Assignment and Asset Purchase Agreement by and between the Company and Spectrum Pharmaceuticals, Inc., dated September 20, 2018 (incorporated by reference to Exhibit 10.4 to Amendment No. 1 to Form S-1 filed on June 7, 2021)

10.5	Exclusive License Agreement by and between the Company and Sphaera Pharma Pte. Ltd., dated October 1, 2017 (incorporated by reference to Exhibit 10.5 to Amendment No. 1 to Form S-1 filed on June 7, 2021)
10.6	Service Agreement by and between the Company and Globavir Biosciences, Inc. dated July 1, 2017 (incorporated by reference to Exhibit 10.6 to Amendment No. 1 to Form S-1 filed on June 7, 2021)
10.7+	Employment Agreement by and between the Company and Shalabh Gupta, M.D., dated May 18, 2021 (incorporated by reference to Exhibit 10.7 to Form S-1 filed on May 21, 2021)
10.8+	Employment Agreement by and between the Company and Pramod Gupta, M.D., dated March 22, 2021 incorporated by reference to Exhibit 10.8 to Form S-1 filed on May 21, 2021)
10.9+	Amendment to Employment Agreement by and between the Company and Pramod Gupta, M.D., dated April 28, 2021 (incorporated by reference to Exhibit 10.9 to Form S-1 filed on May 21, 2021)
10.10#	Master Services Agreement, dated February 8, 2021, by and between Unicycive Therapeutics, Inc. and Ascent Development Services, Inc. (incorporated by reference to Exhibit 10.10 to Form S-1 filed on May 21, 2021)
10.11#	License Agreement effective as of July 14, 2022 by and between Unicycive Therapeutics, Inc. and Lee's Pharmaceutical (HK) Limited (incorporated by reference to Exhibit 10.1 to Form 8-K filed on July 18, 2022)
10.12#	License Agreement effective as of February 1, 2023 by and between Unicycive Therapeutics, Inc. and Lotus International Pte Ltd. (incorporated by reference to Exhibit 10.1 to Form 8-K filed on February 2, 2023)
10.13	Form of Securities Purchase Agreement, dated March 3, 2023, by and between Unicycive Therapeutics, Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 to Form 8-K filed on March 6, 2023)
10.14	Placement Agency Agreement, dated March 3, 2023 by and between Unicycive Therapeutics, Inc. and EF Hutton, division of Benchmark Investments, LLC (incorporated by reference to Exhibit 10.2 to Form 8-K filed on March 6, 2023)
10.15	Form of Amendment No. 1 to Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 to Form 8-K filed on April 10, 2023)
10.16	Form of Exchange Agreement dated March 13, 2024 by and between Unicycive Therapeutics, Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 to Form 8-K filed on March 14, 2024)
10.17	Securities Purchase Agreement, dated March 13, 2024, by and between Unicycive Therapeutics, Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 to Form 8-K filed on March 14, 2024)
10.18+	Second Amended and Restated 2021 Omnibus Equity Incentive Plan (incorporated by reference to Exhibit C to registrant's Proxy Statement on Schedule 14A filed on April 26, 2024
10.19	Manufacturing and Supply Agreement dated as of October 31, 2020 by and between Unicycive Therapeutics, Inc. and Shilpa Medicare Ltd. (incorporated by reference to Exhibit 10.1 to Form 10-Q filed on August 14, 2024)
10.20	First Amendment to Manufacturing and Supply Agreement dated June 25, 2024 by and between Unicycive Therapeutics, Inc. and Shilpa Medicare Ltd. (incorporated by reference to Exhibit 10.2 to Form 10-Q filed on August 14, 2024)
10.21+	Employment Agreement (this "Agreement"), dated August 12, 2024, by and among Unicycive Therapeutics Inc. and Doug Jermasek. (incorporated by reference to Exhibit 10.3 to Form 10-Q filed on August 14, 2024)
14.1	Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14.1 to Form 10-K filed on March 31, 2022).
19.1	Insider Trading Policy, incorporated by reference to Exhibit 19.1 to Form 10-K filed on March 31, 2025
23.1*	Consent of Grassi & Co., CPAs, P.C., independent registered public accounting firm
24.1	Power of Attorney (included on signature page hereto)
31.1*	Certification of Principal Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
31.2*	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1*	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	Clawback Policy (incorporated by reference to Exhibit 97.1 to Form 10-K filed on March 28, 2024
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase.
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

+ Indicates a management contract or any compensatory plan, contract or arrangement.

Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

* Filed herewith

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

UNICYCIVE THERAPEUTICS, INC.

March 30, 2026

/s/ Shalabh Gupta
Shalabh Gupta
Chief Executive Officer (Principal Executive Officer), President and Chairman of the Board of Directors

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Shalabh Gupta as his or her attorney-in-fact, with full power of substitution and resubstitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Shalabh Gupta Shalabh Gupta	Chief Executive Officer, President and Chairman of the Board of Directors (Principal Executive Officer)	March 30, 2026
/s/ John Townsend John Townsend	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2026
/s/ Sandeep Laumas, M.D. Sandeep Laumas, M.D.	Director	March 30, 2026
/s/ Saraswati Kenkare-Mitra, Ph.D. Saraswati Kenkare-Mitra, Ph.D.	Director	March 30, 2026
/s/ Gaurav Aggarwal, M.D. Gaurav Aggarwal, M.D.	Director	March 30, 2026

Exhibit 4.4

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2025, Unicycive Therapeutics, Inc. had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): (i) common stock, $0.001 par value per share ("Common Stock").

Unless the context otherwise requires, all references to "we", "us", the "Company", or "Unicycive" in this Exhibit 4.4 refer to Unicycive Therapeutics, Inc.

DESCRIPTION OF CAPITAL STOCK

The following description of our securities is intended as a summary only and is qualified in its entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the annual report on Form 10-K of which this Exhibit 4.4 is a part.

Authorized Capitalization

Our authorized capital stock consists of 400,000,000 shares of Common Stock and 10,000,000 shares of preferred stock, $0.001 par value per share ("Preferred Stock") in one or more series, of which 21,400 shares have been designated as Series A-2 Prime Convertible Preferred Stock, 25,900 shares have been designated as Series A-2 Prime Convertible Preferred Stock 25,700 shares have been designated as Series A-2 Prime Convertible Preferred Stock 51,600 shares have been designated as Series A-2 Prime Convertible Preferred Stock, 50,000 shares have been designated as Series B-1 Convertible Preferred Stock and 50,000 shares have been designated as Series B-2 Convertible Preferred Stock. As of March 30, 2026, we had outstanding 25,237,782 shares of our Common Stock, 2,265 shares of Series A-2 Prime Convertible Preferred Stock, 0 shares of Series A-3 Convertible Preferred Stock 0 shares of Series A-4 Convertible Preferred Stock, 0 shares of Series A-5 Convertible Preferred Stock, 0 shares of Series B-1 Convertible Preferred Stock and 0 shares of Series B-2 Convertible Preferred Stock.

Transfer Agent and Registrar. The transfer agent for our Common Stock is Pacific Stock Transfer Company.

Listing. Our Common Stock is traded on the Nasdaq Capital Market under the symbol "UNCY."

Common Stock

The holders of our common stock are entitled to one vote per share. Our amended and restated certificate of incorporation, as amended, does not provide for cumulative voting. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of our assets which are legally available; however, the current policy of our board of directors is to retain earnings, if any, for operations and growth. Upon our liquidation, dissolution or winding-up, holders of our common stock are entitled to share in all assets remaining after payment of all liabilities and the liquidation preferences of any of our outstanding shares of preferred stock. The holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock, which may be designated solely by action of our board of directors and issued in the future.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (File No.'s 333-259476, 333-27965 and 333-286305) and the Registration Statements on Form S-3 (File No's .333-266890, 333-273221, 333-280703 and 333-283210) of our report dated March 30, 2026 relating to the financial statements of Unicycive Therapeutics, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ GRASSI & CO., CPAs, P.C.

Jericho, New York
March 30, 2026

Exhibit 31.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Shalabh Gupta, M.D., certify that:

(1) I have reviewed this Form 10-K of Unicycive Therapeutics, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2026

By: /s/ *Shalabh Gupta, M.D.*
Shalabh Gupta, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Townsend, certify that:

(1) I have reviewed this Form 10-K of Unicycive Therapeutics, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2026

By: /s/ *John Townsend*
John Townsend
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Unicycive Therapeutics, Inc. (the "Company") on Form 10-K for the twelve month period ended December 31, 2025, as filed with the Securities and Exchange Commission on March 30, 2026 (the "Report"), I, Shalabh Gupta, M.D., Chief Executive Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for the periods presented in the Report.

By: /s/ Shalabh Gupta, M.D.
Shalabh Gupta, M.D.
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, John Townsend, certify that:

In connection with the Annual Report of Unicycive Therapeutics, Inc. (the "Company") on Form 10-K for the twelve month period ended December 31, 2025, as filed with the Securities and Exchange Commission on March 30, 2026 (the "Report"), I, John Townsend, Chief Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for the periods presented in the Report.

By: /s/ *John Townsend*
John Townsend
Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be furnished to the Securities and Exchange Commission or its staff upon request.