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, 2022

☐ 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.)
4300 El Camino Real, Suite 210 Los Altos, CA	**94022**
(Address of principal executive offices)	(Zip Code)

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

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, 2022 was $12,486,933 based upon the closing price of the registrant's common stock of $0.83 on The Nasdaq Capital Market as of that date.

The number of shares of common stock outstanding as of March 30, 2023 was 15,233,836.

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 2023 Annual Meeting of Stockholders (the "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 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 incurred losses since our inception and anticipate that we will continue to incur increasing losses for the foreseeable future.
- 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 Relating to the Development and Regulatory Approval of Our Product Candidates

- We have a limited number of product candidates, all which are still in early clinical or pre-clinical development. If we do not obtain regulatory approval of one or more of our product candidates, or experience significant delays in doing so, our business will be materially adversely affected.
- Clinical trials are expensive, time consuming, difficult to design and implement, and involve uncertain outcomes. Results of previous pre-clinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or other regulatory authorities.
- We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for which our product candidates are being studied which could delay or prevent the start of clinical trials for our product candidates.
- Our product candidates may have undesirable side effects that may delay or prevent marketing approval or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.
- The FDA may decide that additional nonclinical and clinical studies would be required for the approval of our products.
- The FDA may not agree with the study design and/or interpretation of the data from clinical trials.
- We are dependent on third parties for manufacturing and marketing of our product candidates. If we are not able to secure favorable arrangements with such third parties or the third parties upon whom we rely do not perform, including failure to perform to our specifications or comply with applicable regulations, our business and financial condition could be harmed.
- If any of our product candidates receive regulatory approval, the approved products may not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, in which case revenue generated from their sales would be limited.
- Even if we receive regulatory approval to commercialize any of the product candidates that we develop, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

- If any product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

- Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain for such product candidates. If we fail to comply with regulations, we could face substantial enforcement actions, including civil and criminal penalties and our business, operations and financial condition could be adversely affected.

Risks Relating to our Business and Operations

- If the market opportunities for our current and potential future product candidates are smaller than we believe they are, our ability to generate product revenue may be adversely affected and our business may suffer.

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

- Any international operations we undertake may subject us to risks inherent with operations outside of the United States.

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. We may incur substantial costs as a result of litigation or other proceedings relating to patents and other intellectual property rights.

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.

- Substantial amounts of our outstanding shares may be sold into the market when lock-up or market standoff periods end. If there are substantial sales of shares of our common stock, the price of our common stock could decline.

- 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 Renazorb 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 biotechnology company dedicated to developing treatments for certain medical conditions. Currently, two of our programs are focused on kidney disease, an area we believe we have the potential to offer medical benefit. As we grow the company and build our team, we intend to focus on identifying medical conditions within and outside of kidney disease. Our current development programs are focused on two novel therapies: Renazorb™, for treatment of hyperphosphatemia in patients with chronic kidney disease on dialysis, and UNI 494, for treatment of acute kidney injury (AKI). Renazorb and UNI 494 were initially developed by and licensed to us from Spectrum Pharmaceuticals ("Spectrum") and Sphaera Pharmaceuticals, respectively. Spectrum conducted a Phase 1 clinical trial with Renazorb 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, and performed some initial physiochemical characterization and preliminary animal pharmacokinetic studies. As discussed herein, during 2021 and 2022 we have conducted preclinical studies with UNI 494.

Chronic kidney disease (CKD) is the gradual loss of kidney function that can get worse over time leading to lasting damage. 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. 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). Approximately 550,000 patients with end-stage renal disease (ESRD) are on dialysis and of those, approximately 450,000 take phosphate binders to control hyperphosphatemia. 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 in 2030.

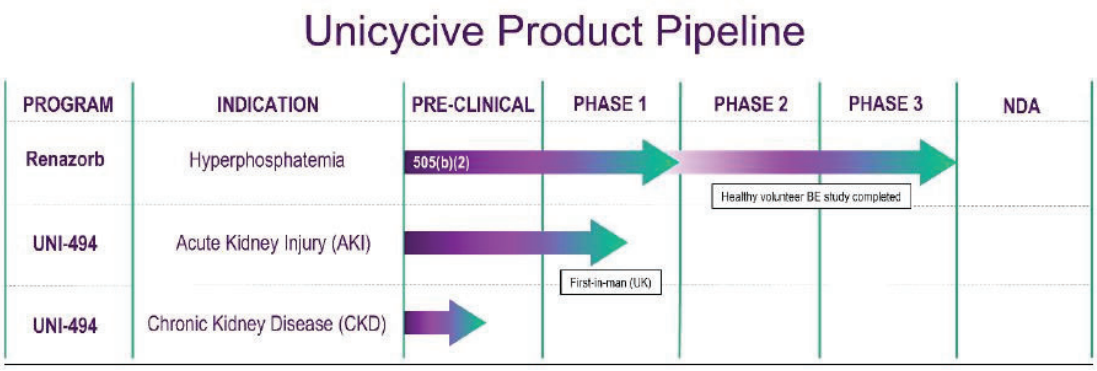
AKI is a sudden episode of kidney failure or kidney damage (within the first 90 days of injury). After 90 days, the patient is considered to have progressed into CKD. AKI affects more than 2 million U.S. patients and costs the healthcare system in excess of $9 billion per year. AKI kills more than 300,000 patients per year in the U.S. and is caused by multiple etiologies.

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.

Pipeline

Our proprietary pipeline is comprised of our two product candidates – Renazorb and UNI 494 – which are described below.

UNI-014 (Renazorb)



Renazorb Purchase Agreement

On September 20, 2018, we entered into an Assignment and Asset Purchase Agreement (the "Renazorb Purchase 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 Renazorb 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 Renazorb Purchase Agreement, in consideration for the Compounds, we issued 313,663 shares of common stock to Spectrum.

Additionally, the Renazorb Purchase 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 Renazorb 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 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 Renazorb Purchase 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 Renazorb Purchase Agreement.

Disease overview: Hyperphosphatemia

Chronic kidney disease (CKD) is the gradual loss of kidney function that can get worse over time leading to lasting damage. The stages of chronic kidney disease are shown below in table 1.

CKD Staging		
CKD Stage	Description	eGFR (mL/min/1.73m²)
1	Normal	>90
2	Mild	60 - 89
3	Moderate	30 - 59
4	Severe	15 - 29
5	End Stage Renal Disease (ESRD)	< 15

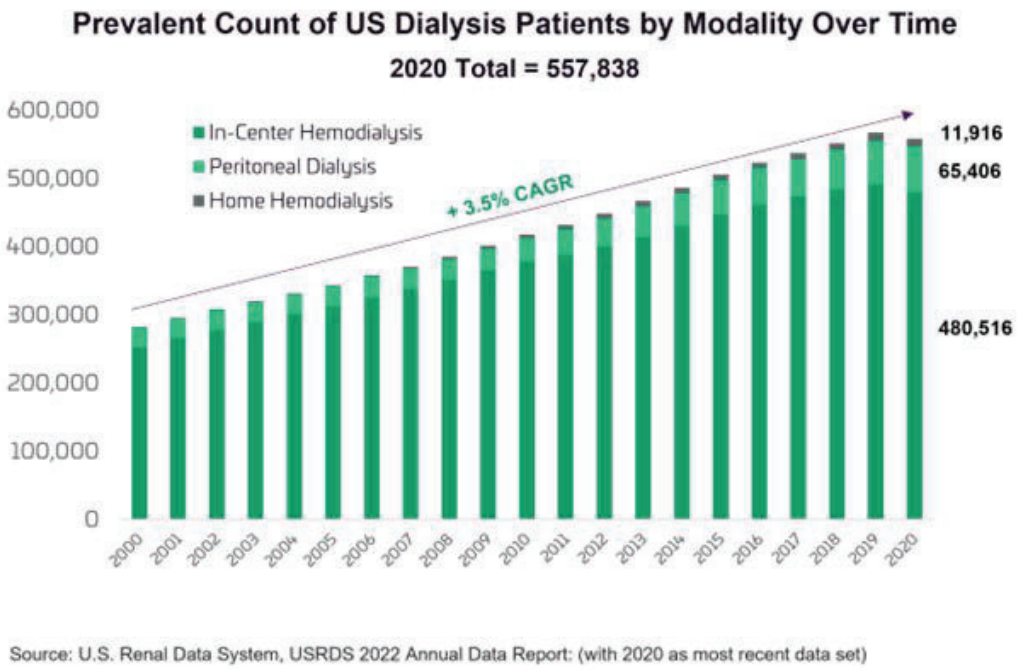
Increasing Severity

Table 1: adapted from The Renal Association (https://renal.org/information-resources/the-uk-eckd-guide/ckd-stages/)

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

Complications of CKD include electrolyte imbalances, fluid build-up, anemia, bone disease, and heart disease. Hyperphosphatemia is an electrolyte disorder in which untreated elevated phosphorus levels in the blood lead to cardiovascular complications and vascular calcification. According to Kidney Disease Improving Global Outcomes (KDIGO) guidelines, hyperphosphatemia is defined as an abnormally high serum phosphorus concentration >4.5 mg/dL In healthy people, phosphorus levels are maintained as phosphate is absorbed from food and excreted in the urine and feces. In people with CKD, not enough phosphate is excreted, leading to elevated levels of phosphorus in the blood. In CKD, hyperphosphatemia is caused by a chronic dysregulation of serum phosphorus levels as a result of progressive kidney damage. According to a 2009 paper authored by Covic, hyperphosphatemia is associated with increased risk of cardiovascular disease, metabolic bone disease, and 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. Hyperphosphatemia is also a major cause of morbidity in CKD patients, which increases the economic and clinical burden on patients and the health system and results in Medicare expenditures of $70 billion in the U.S.

According to the 2022 United States Renal Data System (USRDS), it is estimated that 14% of U.S. adults (approximately 31 million people) have CKD. Most patients with stage 5 CKD either undergo kidney transplant or go on dialysis. The 2022 USRDS annual report indicates that there were 557,838 prevalent dialysis patients in 2020 (the latest reported year). The prevalent U.S. dialysis population has grown at an average yearly rate of 3.5% over the past decade. Furthermore, in a paper published by McCullough in 2019, the number of patients in the U.S. with ESRD is increasing steadily and is projected to reach between 971,000 and 1,259,000 in 2030. In 2020, the number of prevalent dialysis patients declined due to an increased death rate of dialysis patients as a consequence of COVID-19.



Source: U.S. Renal Data System, USRDS 2022 Annual Data Report: (with 2020 as most recent data set)

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: diet restrictions, phosphate binders, and dialysis, as shown in figure 1 below.

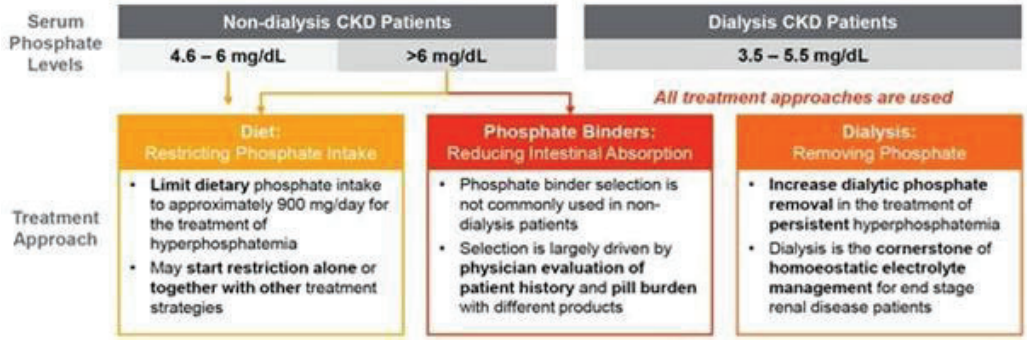


Figure 1: KDIGO guidelines recommend 3 main strategies.

While KDIGO guidelines support the treatment of hyperphosphatemia with phosphate binders in patients with CKD, with the exception of calcium-based binders, they do not recommend one agent over another. This means that physicians prescribe their medication of choice, usually based on clinical and patient factors. 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 and mortality.

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.

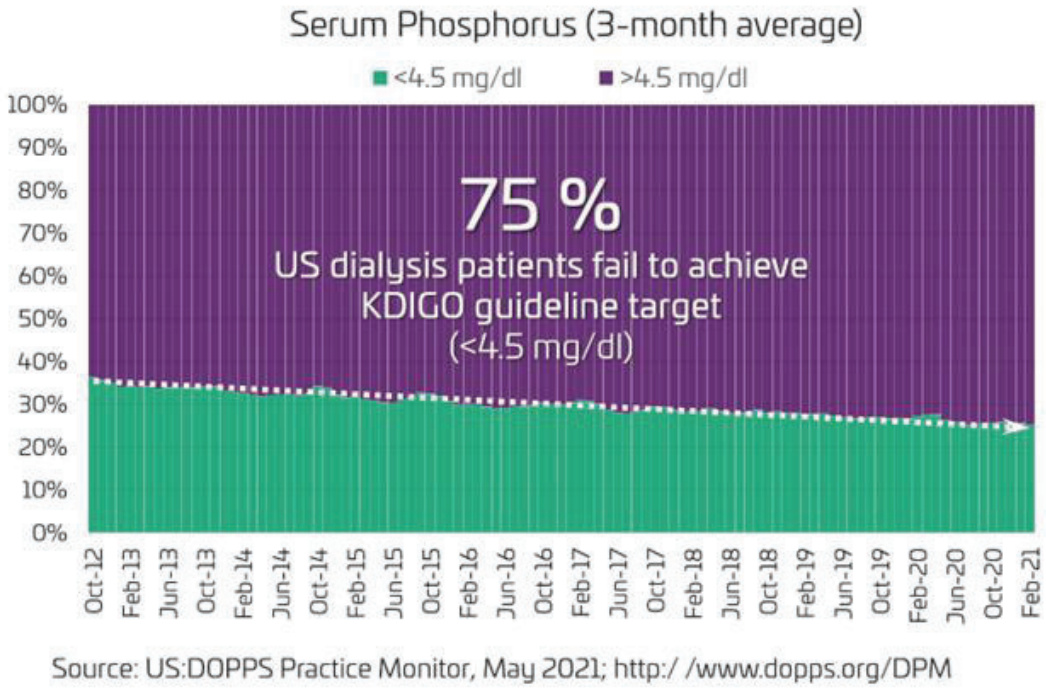
Unmet Medical Need in the Management of Hyperphosphatemia

The mechanism of action and what we believe to be the advantages and disadvantages of various phosphate binders are shown below.

Phosphate Binders	Mechanism of Action	Form	Advantages	Disadvantages	Example 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, Nephrox

Table 2: 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 established by the KDIGO guidelines. Moreover, serum phosphorus outcomes are trending downward—underscoring the need for newer, more effective treatment options.



Source: US:DOPPS Practice Monitor, May 2021; http:/ /www.dopps.org/DPM

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.

Development of Renazorb

Renazorb (lanthanum dioxycarbonate) is an investigational phosphate binding agent utilizing proprietary nanoparticle technology for the treatment of hyperphosphatemia in CKD patients on dialysis.

Renazorb Mechanism of Action

Renazorb binds to phosphates and forms an insoluble lanthanum phosphate complex which is then excreted via the feces. This results in reduction of serum phosphorus levels.

In rat studies, Renazorb 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). 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, Renazorb was superior to sevelamer (the most commonly used phosphate binder) in reducing urine phosphorus excretion (see Fig 2).

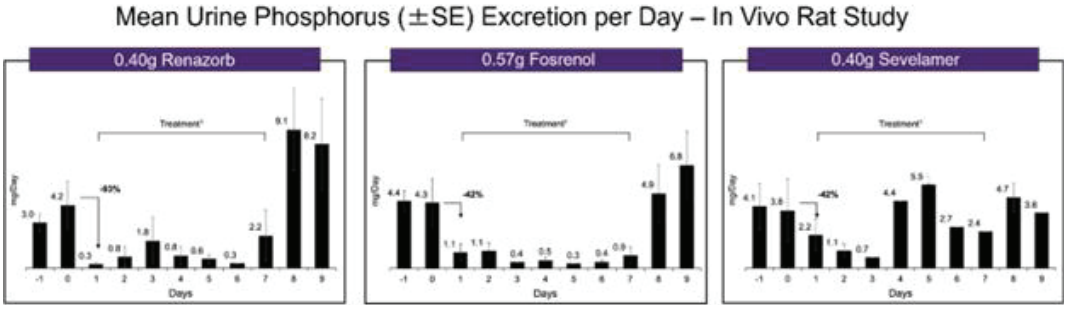


Figure 2: Urine phosphate levels in rats following comparable dosing of Renazorb, Fosrenol, or Sevelamer

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

The chemical design of Renazorb allows for smaller tablet size and fewer pills compared with currently available phosphate binder alternatives, specifically with a dosing regimen of only one tablet per meal. The Renazorb tablet is designed to disintegrate in the stomach after swallowing and disperse the product in a short period of time at a pH ≥3.0.

Clinical Trial Experience

In September 2012 a Phase 1 single-center clinical trial evaluating Renazorb in 32 healthy volunteers was completed in the United States. Four sequential dose cohorts of 8 subjects each (6 actives and 2 placebos) received Renazorb 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 Renazorb as judged by the level of phosphorus in feces and urine. We believe the study indicated that Renazorb was minimally absorbed to the systemic circulation and was well-tolerated at doses up to 6000 mg/day. Renazorb 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.

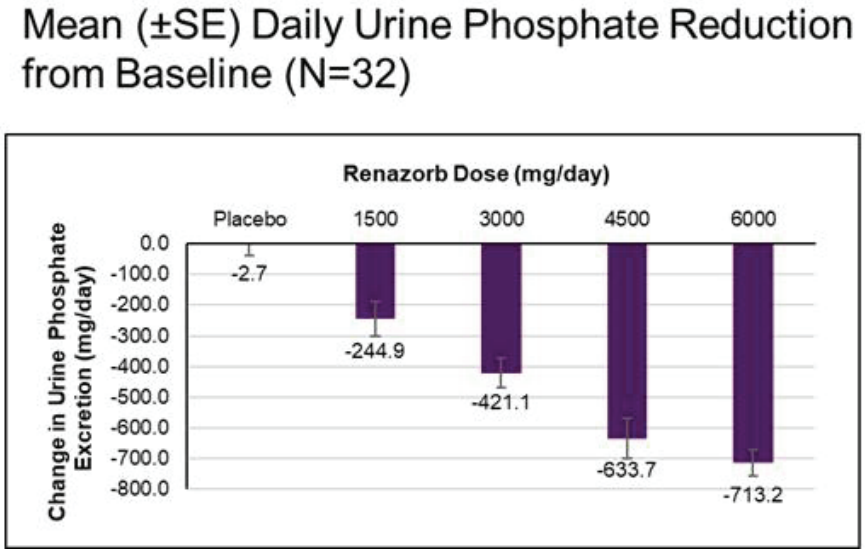


Figure 3: Daily urine phosphate reduction

Regulatory Strategy for Renazorb

Feedback from the FDA

We received additional guidance on the regulatory pathway for Renazorb from the U.S. Food and Drug Administration (FDA) following a Type C meeting in March 2022, in which the FDA confirmed that a single clinical bioequivalence study in healthy volunteers, together with the previously agreed-upon 6-month mouse toxicology study can support the New Drug Application (NDA) filing of Renazorb through a 505(b)(2) pathway.

We reached an agreement with the FDA on the clinical study design including the doses of Renazorb and Fosrenol, sample size and the primary endpoints of the bioequivalence study. The FDA confirmed that no additional clinical studies would be required for the NDA application.

BE Study Description

We conducted a randomized, open label, two-way crossover BE study to establish pharmacodynamic (PD) bioequivalence between Renazorb and Fosrenol. The primary objective of the study was to demonstrate PD equivalence of orally administered Renazorb 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 UNI-014 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 UNI-014 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 UNI-014 (-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 (-45.88, 53.16), which is well within the acceptance range of (-64.80, 64,80) (**Table 3**). It was concluded that UNI-014 was bioequivalent to Fosrenol. Primary outcome data is presented in the table below.

Table 3 Summary of Mean Change in Urinary Phosphorus Excretion (mg/day)

		Phosphorus Excretion (mg/day)	
Visit	**Statistics**	**Renazorb (N=75)**	**Fosrenol (N=75)**
Baseline	LS Mean	859.8	878.1
Evaluation Period	LS Mean	546.7	546.8
Change from Baseline	LS Mean Change	-320.4	-324.0
	90% Confidence Interval for the LS mean (Test-Reference)	(-45.88, 53.16)	
	Acceptance Range	(-64.80, 64.799)	

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 Renazorb, we have entered into an agreement with Shilpa Medicare Ltd based in India. According to the terms of the agreement, following Renazorb approval by the FDA, Unicycive will pay the vendor $2 million in the first calendar year when the net revenue reaches $10 million from sales of Renazorb and commercial supply of the product by the vendor (First Payment). Thereafter, we will pay $2 million per year for four consecutive years, after the first year's payment, for the total payments of $10 million, provided all commercial supplies are continued to be manufactured and supplied by the vendor. Unicycive is not obligated to make any payments to the vendor until FDA approval of the product is obtained and commercial revenue is generated.

Commercial Strategy for Renazorb

The worldwide market for hyperphosphatemia agents is estimated at ~$2.5 billion and is growing at a 5.3% CAGR (Fortune Business Insights, *Hyperphosphatemia Treatment Market, 2021-2028*). According to a study conducted by Syneos Health for the Company, the U.S. market makes up over $1 billion of that total. We own commercial rights to Renazorb globally. For the U.S. market, we intend to maintain optionality by pursuing 3 potential go-to-market models in parallel. We believe that this is the best strategy to maximize both the clinical value of the Renazorb asset for patients and the economic value of the asset to our investors.

1. Launch Renazorb in the U.S. market ourselves by building out a specialty commercial operation to address the highly concentrated nephrology prescription market. Executive management of the company has considerable product launch experience in the nephrology space with specific working knowledge of the hyperphosphatemia market. While there are ~10,000 prescribers of phosphate binders, ~2,500 prescribers are responsible for over half of the ~2.5 million prescriptions written annually. We believe that we can efficiently create demand for Renazorb within the most productive segments of the market with a relatively small salesforce, while addressing the broader segments of prescribers through non-personal and digital promotion tactics.

2. Out-license and/or co-promote Renazorb with an established biopharma company that has an existing commercial infrastructure in the renal disease space.

3. Out-license rights or enter into distribution agreement(s) with dialysis organization(s) for the commercialization of Renazorb.

Collaboration Partners

In July of 2022, we entered into an agreement granting exclusive rights to develop, market and commercialize Renazorb (lanthanum dioxycarbonate) to Lee's Pharmaceutical (HK) in Mainland China, Hong Kong, and certain other Asian markets. Under the terms of the agreement, Lee's Pharm will be responsible for development, registration filing and approval for Renazorb in the licensed territories. In addition, Lee's Pharm will have sole responsibility for the importation of the drug product from Unicycive and for the costs of commercialization of Renazorb in the licensed territories. We received an upfront payment of $1.0 million upon signature and may receive up to $1.0 million in milestone payments upon product launch in China and will be eligible for tiered royalties upon achievement of prespecified regulatory and commercial achievements.

In February of 2023, we entered into an exclusive license agreement with Lotus Pharmaceutical for the development and commercialization of Renazorb in the Republic of Korea. Under the terms of the agreement, Lotus will be responsible for development, registration filing and approval of Renazorb in the Republic of Korea. In addition, Lotus will have sole responsibility for the importation of the drug product from Unicycive and for the costs of commercialization of Renazorb in the Republic of Korea. We received an upfront payment of $750,000 and may receive up to $4.45 million in milestone payments and tiered royalties upon achievement of prespecified regulatory and commercial achievements.

We will continue to seek licensing partners for Renazorb in other territories outside the U.S. (i.e., Europe, Japan, Canada, South America, and the Middle East.)

U.S. opportunity for Renazorb

Renazorb 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 such as Renvela®, Calcium Acetate, Auryxia®, Velphoro®, and Fosrenol involve patients needing to take large numbers and/or large sized, chewable pills each day, which often results in poor adherence to the prescribed drug therapy (Figure 4 below). By virtue of its novel nanoparticle technology, Renazorb 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 Renazorb compared with currently available phosphate binders is likely to lead to improved patient compliance/adherence and more effective disease management.

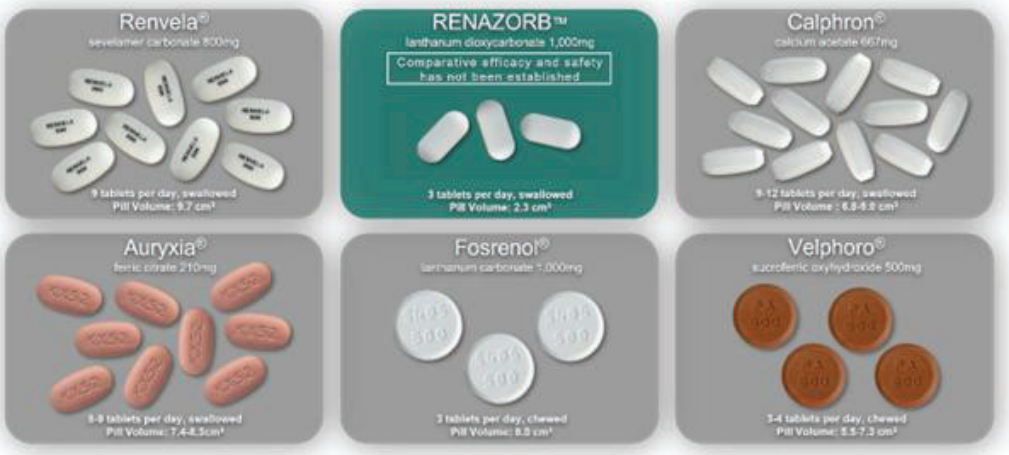


Figure 4: Average daily dose of phosphate binder therapies from www.dailymed.nlm.nih.gov. Product images are proportionally sized.

Tenapanor (Ardelyx): A Potential New Hyperphosphatemia Market Player

Tenapanor is a new oral treatment for hyperphosphatemia that utilizes a novel mechanism of action that inhibits paracellular transport of phosphorus into the bloodstream. Ardelyx filed an NDA for tenapanor with the FDA in June of 2020. In July of 2021, Ardelyx received a Complete Response Letter ("CRL") from the FDA's Division of Cardiology and Nephrology. According to the CRL, the Division characterized the treatment effect of tenapanor as "small and of unclear clinical significance." Ardelyx appealed FDA's decision and ultimately was granted an Advisory Committee meeting in November of 2022, where committee members voted in favor of approving tenapanor (9 to 4 in favor of approving tenapanor as monotherapy and 10 to 2 in favor of its approval in combination with phosphate binders). Ardelyx is in discussions with FDA about the nature of a potential approval of tenapanor and expects that approval in the second half of 2023.

While we can't predict the outcome of these negotiations, we believe that given the modest treatment effect of tenapanor that, regardless of the scope of the indication, the clinical utilization of tenapanor will be predominantly in combination with phosphate binders. In FDA Advisory Committee briefing documents, the efficacy of tenapanor in lowering serum phosphorus levels in dialysis patients in an intent-to-treat (ITT) analysis was 0.70mg/dL. By comparison, in the same document FDA summarized the efficacy of lanthanum carbonate as resulting in a reduction in serum phosphorus of 2.0mg/dL in a comparable ITT analysis of clinical data. Based on this FDA commentary, we would expect Renazorb to be substantially more effective than tenapanor when used as monotherapy. Similar to Renazorb, one of the key features of tenapanor's value proposition is its low pill burden. For this reason, we believe that Renazorb may be the most logical phosphate binder to combine with tenapanor making the two potential new medicines more complimentary than competitive as it would leverage two distinct mechanisms of action to control phosphorus with a much lower pill burden than the current standard of care.

Changing Access and Reimbursement Environment

According to the most recent ESRD PPS "Final Rule" published for 2023, drugs for the treatment of hyperphosphatemia for Medicare beneficiaries, which are currently provided by Medicare Part D insurers are scheduled to be included into the dialysis bundle in 2025 and will be paid for separately by CMS through a Transitional Drug Add-On Payment Adjustment (TDAPA) program for a minimum of 2 years. In the 2023 Final Rule, CMS stated, *"We have seen that incorporating Medicare Part D drugs into the ESRD PPS has had a significant positive effect of expanding access to such drugs for beneficiaries who do not have Medicare Part D coverage." (federalregister.gov/d/2022-13449).* We believe that the timing of this change coincides with our anticipated launch timing of Renazorb and could provide for a more rapid launch uptake and competitive pricing advantages.

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 a 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).

Current treatment of acute kidney injury

Currently there are no FDA approved medicines to treat 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.

Role of Mitochondria in kidney diseases

The kidney has one of the highest mitochondrial densities in the body. Both acute and chronic kidney disease is associated with mitochondrial loss and impaired repair mechanisms, which subsequently result in increased oxidative damage, cellular injury and cell death. AKI and CKD not only form a continuum but are a bidirectional process, wherein maladaptive repair of AKI leads to CKD and patients with underlying CKD conditions are predisposed to the development of AKI. Mitochondrial dysfunction plays a crucial role in both AKI and CKD, as shown in the diagram below. Since mitochondrial dysfunction is an important factor in the pathogenesis of AKI and CKD, mitochondria have emerged as a therapeutic target for treatment of these diseases.

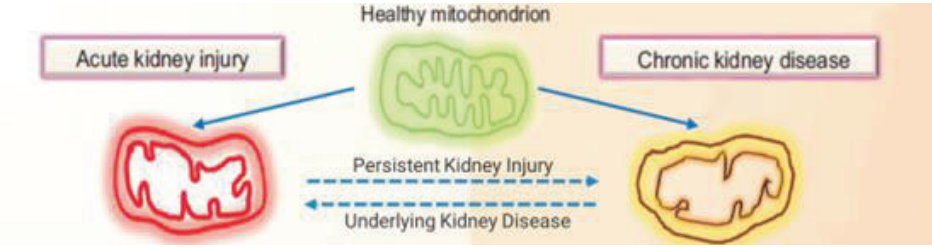


Figure 5
Adapted from Bhatia et al, Kidney Research and Practice 2020 39(3):244-258.

Background on nicorandil

Nicorandil, marketed in such products as Ikorel and Dancor, is indicated for the treatment of chronic stable angina pectoris. It is currently **not** 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.

Nicorandil efficacy in acute kidney injury

Nicorandil has been reported to have a potential protective effect in the kidneys in preclinical studies (Shiraishi 2014, Tamura 2012, Tanabe 2012). In animal studies, nicorandil has demonstrated efficacy in multiple standard models of kidney disease such as ischemic reperfusion injury, 5/6 nephrectomy models of chronic kidney disease, diabetic nephropathy and hypertensive models (see Table 4). Notably, these effects occur in a blood pressure-independent manner, indicating that these beneficial effects are not simply a result of decreasing pressure-mediated kidney damage, but a direct beneficial effect on the kidney. A brief summary from these preclinical studies is provided in the Table below.

Model	Regimen	Outcome	Reference
STZ-induced diabetic nephropathy in eNOS ko mice	Therapeutic – treatment initiated 4 weeks after STZ induction 30 mpk – 30 ug/mL	No decrease in BP but significant reduction in proteinuria, glomerular injury, collagen deposition, and podocyte loss	Tanabe et al., 2012
Anti-Thy1 nephritis in rats	Prophylactic – treatment initiated 3 days before anti-Thy1 injury 10 and 30 mpk	No decrease in BP but significant reduction in proteinuria, renal hypertrophy, collagen deposition, and TGFb expression	Sudo et al., 2009
5/6th nephrectomy in rats	Therapeutic – treatment initiated at time of nephrectomy – 15 mg/kg	No decrease in BP but significant reduction in proteinuria, sCr and BUN, glomerular injury, and tubulointerstitial injury	Shiraishi et al., 2014
Dahl salt-sensitive hypertensive rats	Prophylactic – treatment initiated at time of switch to high salt diet	No decrease in BP but significant reduction in proteinuria, NAG excretion, and oxidative stress	Tashiro et al., 2015
Acute ischemia-reperfusion injury in rats	Therapeutic – treatment initiated 10 min prior to ischemic injury	Significant protection against I-R-induced injury including proteinuria and histological damage	Shimizu 2011
Spontaneously hypertensive WHY rat	Therapeutic – treatment initiated at 11 weeks of age	No decrease in BP but significant reduction in proteinuria, kidney size, and tubular damage	Serizawa et al., 2013

Table 4: Efficacy of nicorandil in standard models of kidney disease

More importantly, several randomized clinical studies have indicated improved renal outcomes with nicorandil in patients with chronic kidney disease, poor renal function, and those undergoing coronary angiography/percutaneous coronary intervention (CAG/PCI). A brief summary from a couple of randomized clinical trials in contrast induced nephropathy (AKI) is described in the table below.

Clinical Setting	Outcome	Reference
Acute Kidney Injury		
Patients with poor kidney function scheduled for PCI (n=213) randomized to saline or nicorandil	• Dose: 0.01 mg/mL cont. infusion; 4 hours before and 24 hours after PCI • Significant reduction in contrast-induced nephropathy (2.0% vs 10.7%, p <0.02) • Reduction in contrast-induced increase in sCr and cystatin C • Control arm showed significant decline in eGFR (-4.2% vs +2.1% ; p<0.001), @ 1 month	**Nawa et al., 2015**
At-risk patients scheduled for PCI (n=128) randomized to placebo or nicorandil	• Dose: 10 mg/day; 30 mins before to 3 days after PCI • Significant reduction in contrast-induced nephropathy (4.7% vs 21.9%, p <0.008) • No change in eGFR from baseline, control arm significant decline in eGFR	**Iranirad et al., 2017**

Table 5: Efficacy of nicorandil in clinical trials in Acute Kidney Injury

In 2020, to bring together the growing evidence of the effectiveness of nicorandil for the prevention of Contrast Induced Nephropathy (CIN). Pranata published the results of a systematic literature review and meta-analysis of clinical studies investigating the use of nicorandil in patients undergoing CAG or PCI. Across the seven trials (sample size N=1,532), nicorandil was shown to decrease the incidence of CIN by 69% (OR: 0.31; 95% CI: 0.20, 0.46; independent of other factors in the respective studies. In addition, a subgroup analysis showed that nicorandil also provided protection against CIN in patients with renal dysfunction (OR: 0.37; 95% CI 0.22, 0.61), which was defined as an eGFR ≤60 mL/min/1.73 m^2. When analyzed by the mode of administration, oral nicorandil was shown to have greater efficacy compared with nicorandil infusions (OR: 0.29 *vs* 0.40). Overall, Pranata *et al.* concluded that nicorandil was associated with a lower risk of CIN in patients undergoing CAG/PCI with a moderate level of certainty (Pranata et al 2020).

Limitations of Nicorandil

Despite these promising results, development of nicorandil for use in acute kidney injury has not been successfully pursued to date. Nicorandil possesses at least two features that may limit its use in this clinical setting. First, nicorandil has a short half-life in humans of approximately 1 hour, which results in the need to dose nicorandil multiple times per day to achieve sustained blood levels. Second, nicorandil has been associated with rare but serious ulcerations in the gastrointestinal tract. The chance of this rare, but potentially severe, side effect increases with higher doses and long-term use of this drug and heals after drug withdrawal. A recent population-based study of this drug's association with GI ulceration or perforation has been reported (Lee et al., Scientific Reports, 2015). This study, based on more than 600,000 randomly selected patients, found a 43% increase in the risk of GI ulceration and a 60% increase in the risk of GI perforation. This effect appears dose-dependent and limits the maximum labeled dose of nicorandil in Europe.

UNI-494: a Pro-drug of Nicorandil

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.

We conducted preclinical studies in rats and dogs demonstrating systemic exposure to nicorandil following oral dosing of UNI-494. In dogs, oral dosing of UNI-494 produced up to four times greater systemic exposure to nicorandil compared with literature data on equimolar doses of nicorandil itself.

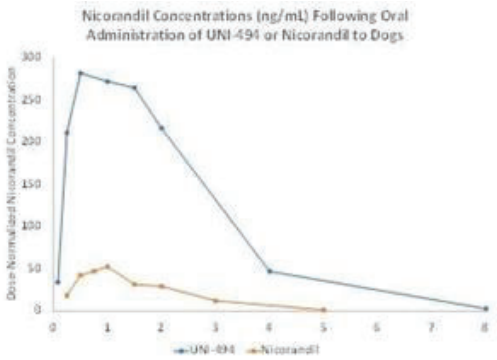


Fig 6

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 the diagram below:

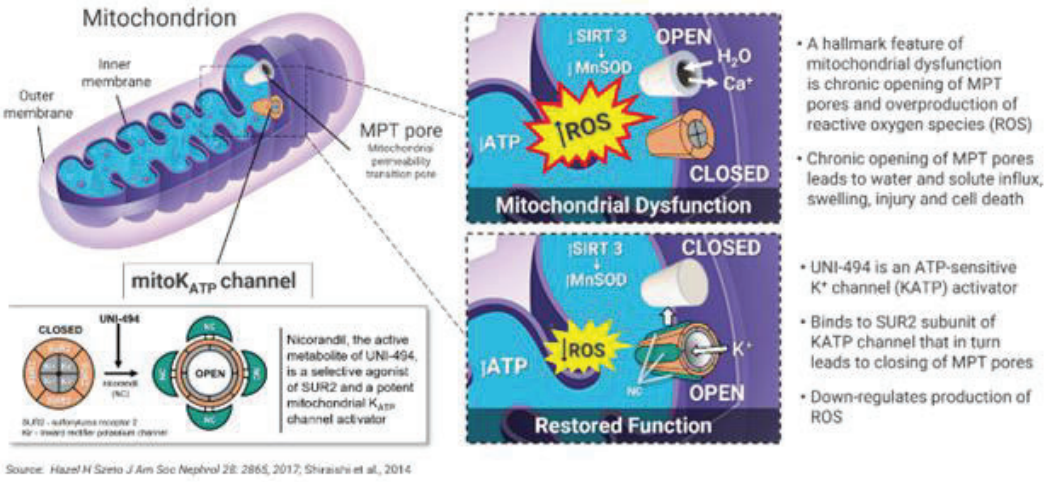


Fig 7

Clinical trials for UNI-494 in AKI

It is challenging to conduct clinical trials in AKI trials due to the multiple etiologies of AKI. We believe that UNI-494 should be evaluated in clinical trials focusing on a few select etiologies in which UNI-494 has a very strong mechanistic rationale based on nicorandil clinical experience in terms of protection of kidney function and secondary benefits.

Based on our understanding of the mechanism of action of the drug, we are in discussions with key opinion leaders (KOLs) to identify the AKI subsets where UNI-494 can be most active and subsets of AKI patients who are most likely to benefit from UNI-494. We are planning to conduct preclinical studies in animal models to further explore the efficacy and development path in the AKI indication. We have also identified patient populations where we would not likely evaluate UNI-494 in clinical trials, including patients with prior history of gastrointestinal ulcerations. This will become exclusion criteria in future clinical trials for UNI-494.

UNI-494 Development Status

We have completed all non-clinical safety assessment studies required for regulatory filing and submitted a Clinical Trial Application (CTA) to the Medicines and Healthcare Products Regulatory Agency (MHRA) to initiate a Phase 1 study in healthy volunteers in the United Kingdom in December 2022. The MHRA has completed review of our CTA and issued a notice of acceptance for UNI-494 first-in-human Phase 1 study in healthy volunteers. We also plan to file a corresponding Investigational New Drug (IND) application with the FDA in 2024 for a Phase 2 proof-of-concept trial in acute kidney injury (AKI) patients.

Regulatory Strategy for UNI-494

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 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

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 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. 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 a 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.

Renazorb Patent Portfolio

Our Renazorb 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 Renazorb 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 Renazorb. 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 Renazorb and related compounds were filed in 2011. Exclusive of patent term extension, the U.S. patents from this family containing claims covering Renazorb has a statutory expiration date in 2031. 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 2031.

In some cases, granted United States patents claiming Renazorb have a longer statutory term than the corresponding foreign patents. 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 Renazorb 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 Renazorb. 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 Renazob 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	May 12, 2031
10,350,240	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 one application that we own. The granted U.S. patent is directed to methods of making UNI 494, and it is expected to expire in 2032. The PCT application is directed to methods of using UNI 494, and to other compositions of matter and their uses. Should U.S. and other global patents issue from this PCT application, they are expected to expire in 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

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 the 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 the 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 its 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, except that oral-only drugs are exempted from inclusion until 2025. In a final ESRD PPS rule published in October 2022, CMS confirmed that it intends to end the oral-only exclusion of hyperphosphatemia drugs from the ESRD PPS on January 1, 2025. At this time a TDAPA (transitional drug add-on payment adjustment) will provide separate payment for hyperphosphatemia drugs for "no less than 2 years" based on the drug's Average Sales Price, or ASP, that will be 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. Although there are several details that need further clarification, including precise timing related to receiving codes to allow for reimbursement under TDAPA, which are typically assigned on a quarterly basis, the rule provides some support for our assumption that all hyperphosphatemia drugs, including Renazorb, will be included in the ESRD PPS bundle and will be eligible for separate payment initially under TDAPA.

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 it 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 Renazorb , 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 Renazorb, UNI-494, and any other product candidate, including those that may be in-licensed or acquired;
- the size of any market in which Renazorb, 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 Renazorb, 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 Renazorb, 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 Renazorb, if approved. If we are unable to successfully commercialize Auryxia, 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, Renazorb 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 Renazorb, 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 Renazorb 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 Renazorb 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 Renazorb, 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 Renazorb, if approved.

Our, or our partners', failure to obtain or maintain adequate coverage, pricing and reimbursement for Renazorb, 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 Renazorb 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 Renazorb, 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 have 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 Renazorb, 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 Renazorb through contracts we negotiate with third party payors for reimbursement of Renazorb, 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 Renazorb 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 Renazorb 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 Renazorb 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 Renzorb, to the formulary, our business may be materially harmed. In addition, we may be unable to sell Renazorb 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 Renazorb 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 Renazorb 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 Renazorb, and any other product or product candidate, including those that may be in-licensed or acquired. Renazorb 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, 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) and Ardelyx, Inc.'s tenapanor (which is approved in the United States for the treatment of adults with irritable bowel syndrome with constipation, and for which the FDA granted an appeal in the fourth quarter of 2022 that will allow Ardelyx to resubmit a new drug application in 2023 with respect to the control of serum phosphorus in adult patients with CKD on dialysis), that may impact the market for Renazorb.

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. Other actions by the Biden 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, 2023, we had 12 full-time employees and no part-time employees. 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 4300 El Camino Real, Suite 210, Los Altos, CA 94022 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 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 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, 2021 and 2022 was $10.0 million and $18.1 million, and our accumulated deficit as of December 31, 2022 was $34.0 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, 2021 and 2022, we had cash of $16.6 million and $0.5 million, respectively. On March 3, 2023, the Company signed a securities purchase agreement with certain healthcare-focused institutional investors that will provide up to $130 million in gross proceeds to Unicycive through a private placement that included initial upfront funding of $30 million. We expect our existing cash as of December 31, 2022 plus the funding received in March 2023 will enable us to fund our operating expenses and capital expenditure requirements for at least 12 months from the date of this Form 10-K. 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, strategic alliances, 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 or debt 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 in March 2023 financing efforts.

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 will result in dilution to our existing stockholders: As of March 30, 2023, subject to Stockholder Approval, the Series A-1 Preferred Stock will be convertible into approximately 61,612,000 shares of common stock. As a result, 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. Additionally, such shares of Series A-1 Preferred Stock contain certain preferences and privileges not applicable to the shares of common stock, which are described further in the Certificate of Designation filed hereto as Exhibit 3.4.

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. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation and taken into receivership by the FDIC. At that time, substantially all of our cash and cash equivalents were held in accounts with Silicon Valley Bank and we could not access such accounts. While we were afforded full access to our accounts on March 13, 2023 as a result of action taken by the U.S. Department of the Treasury, the Federal Reserve and the FDIC under the systemic risk exception, there is no guarantee that the system risk exception will be relied upon to provide access to uninsured deposits and other assets in the future in the event of the closure of a financial institution, or that such access would be afforded in a timely fashion. 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 Renazorb;
- 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. 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;
- 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.

We may be adversely affected by the ongoing coronavirus pandemic.

The outbreak of the novel coronavirus ("COVID-19") has evolved into a global pandemic. The extent to which COVID-19 impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted.

Due to COVID-19, our planned project timelines may be delayed due to reduced availability of human resources or critical supplies needed to carry out such plans.

Moreover, our clinical trials may be affected by COVID-19. Site initiation, participant recruitment and enrollment, participant dosing, availability and distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to COVID-19.

The ultimate impact of COVID-19, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

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. 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 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, 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 nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with U.S. cGMPs or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, 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.

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 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.

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. 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, 2022, we had 12 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.

Our Chief Executive Officer, Dr. Shalabh Gupta, is also the Chief Executive Officer of Globavir Biosciences, Inc. ("Globavir") and may allocate his time to such other business thereby causing conflicts of interest in his determination as to how much time to devote to our affairs. Furthermore, certain members of our Board of Directors are members of the board of directors of Globavir and may allocate their time to, among other ventures, the business of Globavir which may cause conflicts of interest with respect to their determination as to how much time to devote to our affairs. This could have a negative impact on our ability to implement our plan of operation.

Our Chief Executive Officer, Dr. Shalabh Gupta, is also the Chief Executive Officer of Globavir and may not commit his full time to our affairs, which may result in a conflict of interest in allocating his time between our business and the other business. Similarly, certain members of our Board of Directors are members of the board of directors of Globavir and may not commit their full time to our affairs, which may result in a conflict of interest in allocating their time between our business and the other business. Furthermore, neither our Chief Executive Officer, our executive team, nor our directors are obligated to contribute any specific number of his hours per week to our affairs. If other business affairs require our Chief Executive Officer and/or directors to devote more amounts of time to other affairs, including the business of Globavir, it could limit their ability to devote time to our affairs and could have a negative impact on our ability to implement our plan of operation.

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 shut down 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 nonbreaching 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 in defending 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.

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

- expansion of the entities eligible for discounts under the Public Health program.

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 product pricing, which could negatively affect a pharmaceutical manufacturer's business, results of operations, financial condition and prospects.

It is also possible that President Biden will further reform the ACA and other federal programs in a manner that may impact our operations. For example, the Biden administration has indicated that a goal of its administration is to expand and support Medicaid and the ACA and to make high-quality healthcare accessible and affordable. The potential increase in patients covered by government funded insurance may impact our pricing. Further, it is possible that the Biden administration may further increase the scrutiny on drug pricing.

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, the Biden 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. Further, in July 2020, former President Trump issued a number of executive orders that are intended to lower the costs of prescription drug products including one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for discounts for plans, pharmacies, and pharmaceutical benefit managers. No assurance can be given whether these orders will remain in effect under the Biden administration.

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, recommendation 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 Renazorb 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 Renazorb 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.

Our common stock may be delisted from The Nasdaq Capital Market if we fail to comply with continued listing standards.

If we fail to meet any of the continued listing standards of The Nasdaq Capital Market, our common stock could be delisted from The Nasdaq Capital Market. These continued listing standards include specifically enumerated criteria, such as:

- a $1.00 minimum closing bid price;
- stockholders' equity of $2.5 million;
- 500,000 shares of publicly-held common stock with a market value of at least $1 million;
- 300 round-lot stockholders; and
- compliance with Nasdaq's corporate governance requirements, as well as additional or more stringent criteria that may be applied in the exercise of Nasdaq's discretionary authority.

On August 8, 2022, we received a written notice (the "Notice") from the Nasdaq Stock Market LLC ("Nasdaq") notifying us that were not in compliance with Nasdaq Listing Rule 5550(a)(2) (the "Rule"), as the minimum bid price of the Company's common stock has been below $1.00 per share for 30 consecutive business days. On February 1, 2023, Nasdaq notified us that we had not regained compliance with the Rule and were not eligible for a second 180 day period since we did not comply with the minimum $5,000,000 stockholders' equity initial listing requirement for The Nasdaq Capital Market.

We had requested a hearing before the Nasdaq Hearings Panel and on February 28, 2023, Nasdaq granted to us an exception until July 24, 2023 to regain compliance with the Rule.

On March 28, 2023, we received notice from Nasdaq that we had regained compliance with the minimum bid price requirement for continued listing on The Nasdaq Capital Market.

If we fail to comply with Nasdaq's continued listing standards, we may be delisted and our common stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board or OTCQX market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our common stock could depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Finally, delisting of our common stock could result in our common stock becoming a "penny stock" under the Exchange Act.

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, 2022, our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 62% 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 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, 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. In connection with the preparation of our financial statements for the years ended December 31, 2021 and 2022, we concluded that there were material weaknesses in our internal control over financial reporting. 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. Specifically, we lack a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately while maintaining appropriate segregation of duties. While we are taking steps to remediate the material weaknesses in our internal control over financial reporting, we may not be successful in remediating such weaknesses which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. Furthermore, if we remediate our current material weaknesses but identify new material weaknesses in our internal control over financial reporting 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 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

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 28, 2023, there were 73 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 Renazorb by the FDA if obtained, and the commencement of commercial sales.

Sales of Unregistered Securities

On November 28, 2022, we issued 33,500 shares of restricted common stock to RedChip for investor advisory services. The foregoing issuance was made in a transaction not involving a public offering pursuant to an exemption from the registration requirements of the Securities Act in reliance upon Section 4(a)(2) of the Securities Act or Regulation D promulgated under the Securities Act.

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 and 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 biotechnology company dedicated to developing treatments for kidney disease that have the potential to offer medical benefit. Our development programs are focused on the development of two novel therapies: Renazorb, for treatment of hyperphosphatemia in patients with chronic kidney disease, and UNI 494, for treatment of acute kidney injury (AKI).

Chronic kidney disease (CKD) is the gradual loss of kidney function that can get worse over time leading to lasting damage. Our initial focus is developing drugs and getting them approved in the US, and then look to partner with the other global biopharmaceutical companies in the rest of the world. According to estimates by The Centers for Disease Control and Prevention (CDC) in 2019, 37 million (approximately 15%) adults in the United States have CKD and, of these, approximately 2 million patients with CKD stage 3-5, and around 400 thousand patients with end-stage renal disease (ESRD) have hyperphosphatemia. In the European Union (EU), around 20 million (approximately 8%) adults have CKD, more than 1 million CKD stage 3-5 patients, and approximately 180 thousand patients with ESRD have hyperphosphatemia. The number of patients with ESRD is increasing steadily and is projected to reach between 971,000 and 1,259,000 in 2030.

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 over 2 million US patients and costs the healthcare system over $9 billion per year. AKI kills more than 300,000 patients per year in the US and is caused by multiple etiologies.

Our business model is to license technologies and drugs and 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 the Company at an attractive price with limited upfront cost.

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 $10.0 million and $18.1 million for the years ended December 31, 2021 and 2022. As of December 31, 2022, we had an accumulated deficit of $34.0 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 March 3, 2023, we entered into a securities purchase agreement (the "Purchase Agreement") with certain accredited investors (the "Investors"), pursuant to which we agreed to issue and sell, in a private placement (the "Offering"), 30,190 shares of Series A-1 Convertible Preferred Stock, par value $0.001 per share (the "Series A-1 Preferred Stock"), which offering will result in up to $130 million in gross proceeds and initial upfront funding of $30 million.

Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock (the "Certificate of Designation"), each share of Series A-1 Preferred Stock is, subject to the Stockholder Approval (as defined below), convertible into a unit ("Unit") consisting of (i) shares of common stock, par value $0.001 per share (the "Common Stock") and, if applicable, shares of Series A-2 Convertible Preferred Stock, par value $0.001 per share (the "Series A-2 Preferred Stock"), in lieu of Common Stock, (ii) a tranche A warrant to acquire shares of Series A-3 Convertible Preferred Stock (the "Tranche A Warrant"), (iii) a tranche B warrant to acquire shares of Series A-4 Convertible Preferred Stock (the "Tranche B Warrant"), and (iv) a tranche C warrant to acquire shares of Series A-5 Convertible Preferred Stock (the "Tranche C Warrant", together with the Tranche A Warrant and the Tranche B Warrant, the "Warrants"). The shares of Series A-3 Convertible Preferred Stock, Series A-4 Convertible Preferred Stock and Series A-5 Convertible Preferred Stock issuable upon exercise of the Warrants collectively are referred to herein as the "Preferred Warrant Shares". The Tranche A warrants for an aggregate exercise price of approximately $25 million are exercisable until 21 days following our announcement of receipt of FDA approval for Renazorb, the Tranche B warrants for an aggregate exercise price of approximately $25 million are exercisable until 21 days following our announcement of receipt of Transitional Drug Add-On Payment Adjustment ("TDAPA") approval for Renazorb, and the Tranche C Warrant for an aggregate exercise price of approximately $50 million are exercisable until 21 days following four quarters of commercial sales of Renazorb following receipt of TDAPA approval.

Subject to the terms and limitations contained in the Certificate of Designation, the Series A-1 Preferred Stock issued in the Offering will not become convertible until our stockholders approve the issuance of the Units upon conversion of the Series A-1 Preferred Stock and the issuance of all Common Stock upon conversion of the Series A Preferred Stock (as defined below), among other items (the "Stockholder Approval"). On the tenth (10th) Trading Day (as defined in the Certificate of Designation) following the announcement of the Stockholder Approval, each share of Series A-1 Preferred Stock shall automatically convert into a Unit. Subject to the limitations set forth in the Certificate of Designation, at the option of the holder, each share of Series A-2 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 one share of Common Stock.

In addition, in connection with the Offering, we agreed to modify our dividend policy to state that we intend 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 our annual net cash flow from operations following approval of Renazorb by the FDA, if obtained, and the commencement of commercial sales.

The COVID-19 Pandemic and its Impacts on Our Business

In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. This pandemic could result in difficulty securing clinical trial site locations, CROs, and/or trial monitors and other critical vendors and consultants supporting our trial. These situations, or others associated with COVID-19, could cause delays in our clinical trial plans and could increase expected costs, all of which could have a material adverse effect on our business and financial condition. At the current time, we are unable to quantify the potential effects of this pandemic on our future financial statements.

Components of Results of Operations

Revenues

We recognize revenue from product sales or services rendered when control of the promised goods are transferred to a counterparty in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods and services. To achieve this core principle, we apply the following five steps: identify the contract with the client, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to performance obligations in the contract and recognize revenues when or as we satisfy a performance obligation. We may earn licensing revenue in the future if we negotiate business development arrangements with third parties.

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 ("IPR&D"). We expense both internal and external research and development expenses as they 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, consulting, accounting and tax services, including information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses, as well as services incurred pursuant to a services agreement with Globavir Biosciences Inc., a related party.

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 primarily of interest expense related to convertible notes and a loss on conversion of convertible notes.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2022 (in thousands)

	Years Ended December 31,			
	2021	**2022**	**Change**	**% Change**
Licensing revenues:	$ -	$ 951	$ 951	100%
Operating expenses:				
Research and development	6,080	12,436	6,356	105%
General and administrative	2,897	6,567	3,670	127%
Total operating expenses	8,977	19,003	10,026	112%
Loss from operations	(8,977)	(18,052)	(9,075)	101%
Other income (expenses):				
Interest expense	(628)	(6)	622	(99)%
Loss on debt conversion	(431)	-	431	(100)%
Gain on extinguishment of debt	19	-	(19)	(100)%
Total other income (expenses)	(1,040)	(6)	1,034	(99)%
Net loss	$ (10,017)	$ (18,058)	$ (8,041)	80%

Licensing Revenues

Licensing revenues increased approximately $1.0 million, or 100%, from the prior year due to a licensing agreement entered into with Lee's Pharmaceutical (HK) Limited in July 2022. We received an upfront payment of approximately $1.0 million. There was no comparable revenue earned in the prior period. We may earn additional licensing revenue in the future if we negotiate business development arrangements with third parties.

Research and Development Expenses

Research and development expenses increased by approximately $6.4 million, or 105%, from $6.1 million for the year ended December 31, 2021 to $12.4 million for the year ended December 31, 2022. The increase in research and development expenses was primarily due to an increase in development costs of $6.5 million due to product formulation, clinical study, and preclinical study services in the current period. New employee hires increased labor costs $1.6 million, and consulting and other costs increased $756,000 from the prior period. The increase was partially offset by a $2.2 million decrease in non-cash expense from the issuance of common stock in 2021 pursuant to the anti-dilution clause in the purchase of in process research and development technology from Spectrum Pharmaceuticals, Inc. In addition, non-cash stock compensation costs decreased $338,000 from the prior period.

General and Administrative Expenses

General and administrative expenses increased by approximately $3.7 million, or 127%, from $2.9 million for the year ended December 31, 2021 to $6.6 million for the year ended December 31, 2022 primarily due to an increase of $1.4 million in consulting and professional services costs. Labor costs increased $747,000 due to hiring of new employees. Non-cash stock compensation costs increased $419,000. Insurance expense for directors and officers increased $525,000, and rent, travel, supplies and other costs increased $567,000.

Other Income (Expenses)

Other income (expenses) decreased by approximately $1.0 million, or 99% from $1.0 million for the year ended December 31, 2021 to approximately $6,000 for the year ended December 31, 2022. The decrease was due primarily to decreased interest expense incurred on our convertible notes of $0.6 million as well as conversion to equity of our outstanding convertible notes as a result of our IPO in 2021 which resulted in a non-cash loss on debt conversion of $0.4 million.

Liquidity and Capital Resources

Sources of Liquidity

Since our formation through December 31, 2020, we have funded our operations with the sale of common stock, convertible notes and from a loan from our Chief Executive Officer and principal stockholder. During 2021 we raised $1.1 million through the issuance of convertible notes to investors.

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. We have generated approximately $1.6 million in licensing revenue to date.

Future Funding Requirements

We have incurred net losses since our inception. For the year ended December 31, 2022, we had a net loss of $18.1 million, and we expect to incur substantial additional losses in future periods. As of December 31, 2022, we had an accumulated deficit of $34.0 million.

On March 6, 2023, we announced completion of a securities purchase agreement with certain healthcare-focused institutional investors that will provide up to $130.0 million in gross proceeds through a private placement and that includes initial upfront funding of $30.0 million. Proceeds from the offering will be used to support our NDA submission with the FDA for approval of Renazorb for the treatment of hyperphosphatemia in the U.S. and, if approved, for the commercial launch of Renazorb in the U.S.

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, and after receiving the net proceeds of $28.1 million from a private placement financing, 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.

Related Party Payable

We entered into a Service Agreement with Globavir Biosciences, Inc. ("Globavir"), a related party (the "Service Agreement"). Globavir provides administrative and consulting services and shared office space and other costs in connection with the Company's drug development programs. The initial amended term of the Service Agreement expired on December 31, 2020, and the agreement automatically renews for successive one month periods after the initial termination date. Pursuant to the Service Agreement, the Company paid Globavir $50,000 per month through December 31, 2019 and $10,000 per month commencing on January 1, 2020. During the fourth quarter of 2021, after initially determining that future services under the Service Agreement were no longer required, the Company wrote off the $28,000 remaining prepaid balance due from Globavir as of December 31, 2021. During the year ended December 31, 2022, after determining that although a shared office space is no longer utilized, consulting services continued to be provided, the Company amended the Service Agreement to reflect the consulting services at a reduced service fee of $6,000 per month and a termination date of June 30, 2022.

Convertible Notes

In January through May 2021, we issued convertible notes (the "2021 Notes") in the aggregate principal amount of $1,098,000. The 2021 Notes bear interest at a rate of 12% per annum, payable at maturity, and mature between January and May, 2022. The 2021 Notes shall automatically convert into shares of common stock upon the closing of a financing pursuant to which we receive gross proceeds of at least $500,000 (a "Qualified Financing") or upon a change of control. The 2021 Notes shall convert into such numbers of shares of common stock equal to the conversion amount divided by the Conversion Price. "Conversion Price" means (i) in the event of a Qualified Financing, 70% of the price per share (or conversion price, as applicable) of common stock (or securities convertible into common stock, as applicable) sold in such financing or (ii) in the event of a change of control, the price per share reflected in such transaction.

We accounted for the 2021 Notes as stock-settled debt and we were accreting the carrying amount of the 2021 Notes to the settlement amount through maturity.

In July and through November 2020, we issued convertible notes (the "2020 Notes") in the aggregate principal amount of $1,290,000. The 2020 Notes bear interest at a rate of 12% per annum, payable at maturity, and mature between July and November 2021. The 2020 Notes shall automatically convert into shares of common stock upon the closing of a financing pursuant to which we receive gross proceeds of at least $500,000 (a "Qualified Financing") or upon a change of control. The 2020 Notes shall convert into such numbers of shares of common stock equal to the conversion amount divided by the Conversion Price. "Conversion Price" means (i) in the event of a Qualified Financing, 70% of the price per share (or conversion price, as applicable) of common stock (or securities convertible into common stock, as applicable) sold in such financing or (ii) in the event of a change of control, the price per share reflected in such transaction.

We accounted for the 2020 Notes as stock-settled debt and we are accreting the carrying amount of the 2020 Notes to the settlement amount through maturity. As of December 31, 2020, unpaid and accrued interest of $53,000 as well as debt discount accretion expense of approximately $186,000 was included with the convertible notes on the balance sheet.

Interest expense, including discount accretion expense for the 2021 and 2020 Notes was $238,000 and $627,000 for the years ended December 31, 2020 and 2021, respectively.

As a result of our initial public offering on July 13, 2021, approximately $2,387,000 of principal and $191,000 of unpaid accrued interest related to the 2021 and 2020 Notes was converted into shares of common stock. The conversion resulted in a loss of $431,000 that is included as loss on debt conversion in the accompanying statements of operations for the year ended December 31, 2021.

Private Placement

On March 3, 2023, we entered into a securities purchase agreement (the "Purchase Agreement") with certain accredited investors (the "Investors"), pursuant to which we issued and sold, in a private placement, 30,190 shares of Series A-1 Convertible Preferred Stock, par value $0.001 per share, which offering will result in up to $130 million in gross proceeds and initial upfront funding of $30 million. For more information on the private placement offering, please refer to the section titled "Item 1. Business – Recent Developments".

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,	
	2021	**2022**
Net cash (used in) provided by:		
Operating activities	$ (5,767)	$ (15,651)
Investing activities	(29)	(2)
Financing activities	22,375	(471)
Net (decrease) increase in cash	$ 16,579	$ (16,124)

Cash Flows from Operating Activities

Net cash used in operating activities was $15.7 million for the year ended December 31, 2022. Cash used in operating activities was primarily due to the use of funds for director and officer insurance premiums, development costs associated with our drug candidates, labor costs, consulting and accounting services, and other corporate expenditures for investor relations, compliance, and legal services. We incurred a net loss of $18.1 million after including the effect of non-cash adjustments for stock compensation.

Net cash used in operating activities was $5.8 million for the year ended December 31, 2021. Cash used in operating activities was primarily due to the use of funds for director and officer insurance premiums, development costs associated with our drug candidates, labor costs, consulting and accounting services, and other corporate expenditures for investor relations, compliance, and legal services. We incurred a net loss of $10.0 million after including the effect of non-cash adjustments for stock issuance, stock compensation, and a loss on the conversion of our convertible debt.

Cash Flows from Investing Activities

Net cash used in investing activities was $2,000 for the year ended December 31, 2022 and was due to the purchase of furniture and fixtures for our corporate office. Net cash used in investing activities was $29,000 for the year ended December 31, 2021 and was due to the purchase of furniture and fixtures for our corporate office.

Cash Flows from Financing Activities

Net cash used by financing activities was $471,000 for the year ended December 31, 2022 and was due primarily to payments made pursuant to our financed director and officer insurance policies.

Net cash provided by financing activities was $22.4 million for the year ended December 31, 2021 and was primarily related to proceeds received from our initial public offering, net of issuance and deferred offering costs. In addition, we issued convertible notes to investors for $1.1 million as well as the receipt of $0.1 million in proceeds from the exercise of options. Net repayments on loans from our chief executive officer offset the cash inflows by $1.1 million.

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 revenue, research and development and stock-based compensation. There have been no material changes to our critical accounting policies and estimates during the year ended December 31, 2022 from those used for the year ended December 31, 2021. The below policies represent our critical accounting policies.

Revenue Recognition

We implemented ASC 606, Revenue from Contracts with Customers. This included the development of new policies based on the five-step model provided in the new revenue standard, ongoing contract review requirements, and gathering of information provided for disclosures. We recognize revenue from product sales or services rendered when control of the promised goods are transferred to a counterparty in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods and services. To achieve this core principle, we apply the following five steps: identify the contract with the client, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to performance obligations in the contract and recognize revenues when or as we satisfy a performance obligation.

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 and allocated overheads, including information technology costs and utilities and expenses for issuance of shares pursuant to anti-dilution clause in the purchase of IPR&D technology. 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, and the risk-free interest rate.

JOBS Act

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 $1.2 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 Note 2 to our audited financial statements found elsewhere in this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our financial statements.

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, 2022 and 2021, and the related statements of operations, stockholders' (deficit) equity, and cash flows for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, 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 audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

We have served as the Company's auditor since 2019.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
March 30, 2023

Unicycive Therapeutics, Inc.

Balance Sheets
(in thousands, except for share and per share amounts)

	As of December 31, 2021	As of December 31, 2022
Assets		
Current assets:		
Cash	$ 16,579	$ 455
Prepaid expenses and other current assets	1,832	2,189
Total current assets	18,411	2,644
Right of use asset, net	305	152
Property, plant and equipment, net	28	22
Total assets	$ 18,744	$ 2,818
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 742	$ 892
Accrued liabilities	1,212	2,237
Operating lease liability - current	151	155
Total current liabilities	2,105	3,284
Operating lease liability – long term	155	-
Total liabilities	2,260	3,284
Commitments and contingencies (Note 9)		
Stockholders' (deficit) equity:		
Preferred stock: $0.001 par value per share—10,000,000 shares authorized at December 31, 2021 and 2022; no shares issued and outstanding at December 31, 2021 and 2022	$ -	$ -
Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2021 and 2022; 14,996,534 shares issued and outstanding at December 31, 2021, and 15,231,655 shares issued and outstanding at December 31, 2022	15	15
Additional paid-in capital	32,408	33,516
Accumulated deficit	(15,939)	(33,997)
Total stockholders' equity (deficit)	16,484	(466)
Total liabilities and stockholders' equity (deficit)	$ 18,744	$ 2,818

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.

Statements of Operations
(in thousands, except for share and per share amounts)

	Year Ended December 31, 2021	Year Ended December 31, 2022
Licensing revenues	$ -	$ 951
Operating expenses:		
Research and development	6,080	12,436
General and administrative	2,897	6,567
Total operating expenses	8,977	19,003
Loss from operations	(8,977)	(18,052)
Other expenses:		
Interest expense	(628)	(6)
Loss on debt conversion	(431)	-
Gain on extinguishment of debt	19	-
Total other expenses	(1,040)	(6)
Net loss	$ (10,017)	$ (18,058)
Net loss per share, basic and diluted	$ (0.86)	$ (1.20)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	11,675,750	15,057,049

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.

Statements of Stockholders' (Deficit) Equity
(in thousands, except share amounts)

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders' (Deficit)
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2020	-	$ -	8,514,070	$ 9	$ 3,242	$ (5,922)	$ (2,671)
Net loss	-	-	-	-	-	(10,017)	(10,017)
Net proceeds from initial public offering	-	-	5,000,000	5	22,266	-	22,271
Conversion of convertible notes into common stock	-	-	736,773	1	3,684	-	3,685
Issuance of common stock for exercise of options	-	-	307,317	-	59	-	59
Issuance of common stock for anti-dilution clause	-	-	438,374	-	2,191	-	2,191
Stock-based compensation expense	-	-	-	-	966	-	966
Balance at December 31, 2021		-	14,996,534	15	32,408	(15,939)	16,484
Net loss	-	-	-	-	-	(18,058)	(18,058)
Issuance of common stock for cash, net of issuance costs	-	-	108,032	-	11	-	11
Issuance of common stock	-	-	33,500	-	21	-	21
Issuance of common stock for vested restricted stock units	-	-	26,738	-	-	-	-
Issuance of common stock for exercise of options	-	-	66,851	-	29	-	29
Stock-based compensation expense	-	-	-	-	1,047	-	1,047
Balance at December 31, 2022	-	$ -	15,231,655	$ 15	$ 33,516	$ (33,997)	$ (466)

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.

Statements of Cash Flows
(in thousands)

	Year Ended December 31, 2021	Year Ended December 31, 2022
Cash flows from operating activities		
Net loss	$ (10,017)	$ (18,058)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	1	7
R&D expense for issuance of common stock for anti-dilution clause	2,191	-
G&A expense for issuance of common stock	-	21
Stock-based compensation expense	966	1,047
Convertible debt discount amortization	488	-
Amortization of operating lease right of use asset	12	154
Convertible debt non-cash interest	139	-
Gain on extinguishment of debt	(19)	-
Deferred compensation to CEO	146	-
Loss on debt conversion	431	-
Changes in assets and liabilities:		
Prepaid expense and other current assets	(1,325)	62
Accounts payable and accrued liabilities	1,241	1,267
Operating lease liability	(12)	(151)
Related party service fee payable	(9)	-
Net cash used in operating activities	(5,767)	(15,651)
Cash flows from investing activities		
Purchases of property, plant and equipment	(29)	(2)
Net cash used in investing activities	(29)	(2)
Cash flows from financing activities		
Net proceeds from initial public offering	22,271	-
Issuance of common stock for cash, net of issuance costs	-	11
Proceeds from loan from stockholder	248	-
Proceeds from convertible notes	1,098	-
Repayment of loan from stockholder	(1,361)	-
Payments on financed insurance policies	-	(482)
Proceeds from exercise of options	119	-
Net cash provided by (used in) financing activities	22,375	(471)
Net increase (decrease) in cash	16,579	(16,124)
Cash at the beginning of the period	-	16,579
Cash at the end of the period	$ 16,579	$ 455
Supplemental cash flow information		
Deferred preclinical charges included in prepaid expenses and other current assets	$ 503	$ 420
Deferred insurance charges included in prepaid expenses and other current assets	$ -	$ 240
Cash paid for income taxes	$ -	$ -

See accompanying notes to the financial statements

Notes to the Financial Statements

1. Organization and Description of Business

Overview

Unicycive Therapeutics, Inc. ("the Company") was incorporated in the State of Delaware on August 18, 2016. The Company was dormant until July 2017 when it began evaluating a number of drug candidates for in-licensing.

The Company in-licensed the drug candidate UNI 494 from Sphaera Pharma Pte. Ltd, a Singapore-based corporation, ("Sphaera") (Note 3). 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 ("Renazorb") and its trademark, RENALAN, and various patents from Spectrum Pharmaceuticals, Inc. ("Spectrum") (Note 3). Renazorb 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, targeting orphan diseases and other renal, liver and other metabolic diseases affecting fibrosis and inflammation.

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 generated approximately $1.0 million in licensing revenue through December 31, 2022.

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 increases its research and development activities, the operating losses are expected to increase. The Company has historically relied on private equity offerings, debt financings and loans from a stockholder to fund its operations. As of December 31, 2021 and 2022, the Company had an accumulated deficit of $15.9 million and $34.0 million, respectively.

As a result of 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 6, 2023, the Company announced it has signed a securities purchase agreement with certain healthcare-focused institutional investors that will provide up to $130.0 million in gross proceeds through a private placement and that includes initial upfront funding of $30.0 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. From January 2021 through May 2021, the Company received an aggregate of $1.1 million upon the issuance of convertible notes. These funds were used primarily to settle outstanding accounts payable as well as to make payments on the loan outstanding from the chief executive officer and principal stockholder. In 2021, the Company received approximately $22.3 million in net proceeds from its IPO, and in March 2023 the Company received approximately $28.1 million in net proceeds from a private placement financing. 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 current level of expenditures, and after receiving the proceeds from the private placement in March 2023, 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").

All common share amounts and per share amounts have been adjusted to reflect a 1-for-4.3 reverse stock split of the Company's common stock that was effected on June 21, 2021.

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. Actual results may materially differ from those estimates.

Segment Information

The Company operates and manages its business as one reportable operating segment. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance.

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 downturns (including the current downturn related to the COVID-19 pandemic), 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, Plant and Equipment

Property, plant 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. 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 loss is recognized to write down the asset to its estimated fair value at that time. At December 31, 2021, 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. Right-of-use assets and lease liabilities are recognized at lease commencement based upon the estimated present value of unpaid lease payments over the lease term. 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 cash, prepaid expenses, accounts payable, and in prior periods also included convertible notes and a loan from the Chief Executive Officer and stockholder of the Company. The carrying amounts of these items approximate fair value as of December 31, 2021 and 2022 due to their short-term nature.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash. All of the Company's cash was deposited in one account at a financial institution during 2021 and 2022, and the account balance may at times exceed federally insured limits. The cash and cash equivalents we use to satisfy our working capital and operating expense needs are currently held in accounts at various financial institutions. 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.

Prepaid Expenses

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

Revenue Recognition

The Company has implemented ASC 606, Revenue from Contracts with Customers. This guidance included the development of new policies based on the five-step model provided in the new revenue standard, ongoing contract review requirements, and gathering of information provided for disclosures. The Company recognizes revenue from product sales or services rendered when control of the promised goods are transferred to a counterparty in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods and services. To achieve this core principle, we apply the following five steps: identify the contract with the client, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to performance obligations in the contract and recognize revenues when or as the Company satisfies a performance obligation.

Research and Development Expenses

Substantially all of 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 and allocated overheads, including information technology costs and utilities and expenses for issuance of shares pursuant to the anti-dilution clause in the purchase of IPR&D technology. The Company expenses both internal and external research and development expenses as they are 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 as well as costs from a service agreement with a related party (See Note 8).

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 estimated fair value (prior to the Company's initial public offering) or the public market closing price of the Company's underlying common stock on the date of grant.

Common Stock Valuations

The Company is required to periodically estimate the fair value of common stock when issuing stock options and computing their estimated stock-based compensation expense. The fair value of common stock prior to the Company's initial public offering was determined on a periodic basis, with the assistance of an independent third-party valuation expert. The assumptions underlying these valuations represented Management's best estimates, which involved inherent uncertainties and the application of significant levels of Management judgment.

In order to determine the fair value, the Company considered, among other things, contemporaneous transactions involving the sale of the Company's common stock to unrelated third parties; the lack of marketability of the Company's common stock; and the market performance of comparable publicly traded companies.

Income Taxes

The Company accounts for corporate income taxes in accordance with GAAP as stipulated in ASC, Topic 740, 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 relate 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.

The Tax Cuts and Jobs Act of 2017 eliminated the option to immediately deduct research and development expenditures in the year incurred under Section 174, which became effective January 1, 2022. We are monitoring legislation for any further changes to Section 174 and the impact, if any, to the financial statements in 2023.

Comprehensive Loss

Comprehensive loss includes all changes in equity (net assets) during a period from non-owner sources. There were no elements of other comprehensive income (loss) in the periods presented, as a result comprehensive loss is the same as net loss for each period presented.

Net Loss per Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, common stock options and warrants are considered to be potentially dilutive securities. Basic and diluted net loss per share is presented in conformity with the two-class method required for participating securities. The Company has no participating securities and as such, the net loss was attributed entirely to common stockholders. As the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods. All common share amounts and per share amounts have been adjusted to reflect a 1-for-4.3 reverse stock split of the Company's common stock that was effectuated on June 21, 2021.

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.

In August 2020, the FASB issued ASU 2020-06, Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the accounting for convertible instruments. ASU 2020-06 eliminates certain models that require separate accounting for embedded conversion features. Additionally, among other changes, the guidance eliminates certain of the conditions for equity classification for contracts in an entity's own equity. The guidance also requires entities to use the if-converted method for all convertible instruments in the diluted earnings per share calculation and include the effect of share settlement for instruments that may be settled in cash or shares, except for certain liability-classified share-based payment awards. This guidance is effective for the Company beginning in the first quarter of 2022 and must be applied using either a modified or full retrospective approach. Early adoption is permitted, but no earlier than annual periods beginning after December 15, 2020. The Company adopted the standard on January 1, 2022 using a modified retrospective approach, and the adoption did not result in any adjustments on the Company's financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU requires a lessee to recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the leases with a term of greater than 12 months. This ASU is effective for the Company's fiscal years beginning after December 15, 2021, with early adoption permitted. The Company has adopted this standard effective as of January 1, 2019. The Company chose to adopt the package of practical expedients available from the FASB. As a policy election, the Company chose to expense and amortize, on a straight line, the leases with terms less than 12 months. In addition, the Company chose not to separate certain lease and non-lease components when evaluating the fair value of a lease. The adoption of this standard did not have a material effect on the Company's financial statements.

3. Significant Agreements

With regards to manufacturing, testing and potential commercial supply of Renazorb, the Company has entered into an agreement with Shilpa Medicare Ltd based in India. According to the terms of the agreement Unicycive will pay the vendor $2 million in the first calendar year when the net revenue reaches $10 million from sales of Renazorb following its approval by the FDA and commercial supply of the product by the vendor (First Payment). Thereafter, the Company will pay $2 million per year for four consecutive years, after the first year's payment, for the total payments of $10 million, provided all commercial supplies are continued to be manufactured and supplied by the vendor. Unicycive is not obligated to make any payments to the vendor until FDA approval of the product is obtained and commercial revenue is generated.

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 rather 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. At the time 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 on 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 Renazorb and related compounds. In partial consideration for the Spectrum Agreement, the Company issued 313,663 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 Renazorb 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 438,374 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 Renazorb 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 Renazorb 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 of 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 Renazorb Purchase Agreement) and 20% of all other sublicense income. The Company's payment obligations to Spectrum will expire on the twentieth (20^{th}) anniversary of the Closing Date of the Renazorb Purchase Agreement. In August 2022, the Company received an upfront payment of approximately $1.0 million as a result of a sublicense development agreement with Lee's Pharmaceutical (HK) Limited. 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, 2022.

On July 19, 2021, the Company entered into an agreement with Syneos Health LLC ("Syneos") pursuant to which Syneos will provide preclinical research and analysis services related to the development of UNI-494. The initial budget for the study, which includes clinical pharmacology, translational sciences, and bioanalytical services, was approximately $2.3 million. Related payments totaling approximately $1.8 million have been paid to Syneos as of December 31, 2022, and approximately $0.2 million has been recorded as accounts payable or accrued expense in the accompanying balance sheet as of December 31, 2022.

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 $2.6 million. Related payments totaling approximately $1.5 million have been paid to Quotient as of December 31, 2022, approximately $0.9 million of related expense has been recorded, and approximately $1.0 million has been recorded as prepaid expense in the accompanying balance sheet as of December 31, 2022.

On February 9, 2022, the Company entered into a Master Services Agreement with CBCC Global Research Inc. ("CBCC"), a California based company that provides clinical trial and related services, for the purpose of performing clinical research in support of Renazorb. The budget for the initial study was approximately $1.4 million. Payments relating to the initial agreement totaling approximately $0.4 million have been paid to CBCC as of December 31, 2022, and approximately $0.4 million of related expense has been recorded. In September 2022, a statement of work revised the remaining services budget to approximately $0.1 million.

On June 29, 2022, the Company entered into an Agreement with Inotiv, an Indiana based company that provides preclinical trial and related services, for the purpose of performing research in support of Renazorb. The budget for the services is approximately $1.0 million. Approximately $0.7 million has been paid to Inotiv as of December 31, 2022 and approximately $0.4 million has been recorded as prepaid expense in the accompanying balance sheet as of December 31, 2022.

On July 14, 2022, the Company entered into a license agreement with Lee's Pharmaceutical (HK) Limited (see Note 4). Under the terms of the agreement, Lee's Pharmaceutical will be responsible for development, registration filing and approval for Renazorb 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 Renazorb 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 July 27, 2022, the Company entered into an Agreement with Celerion, a Nebraska based company that provides clinical trial and related services, for the purpose of performing research in support of Renazorb. The budget for the services is approximately $2.7 million, and approximately $2.7 million has been paid to Celerion as of December 31, 2022.

4. Licensing Revenues

On July 14, 2022, the Company entered into a license agreement ("Agreement") with Lee's Pharmaceutical (HK) Limited ("Lee's"). Under the terms of the agreement, Lee's Pharmaceutical will be responsible for development, registration filing and approval for Renazorb in China, Hong Kong, and certain other Asian markets. In addition, Lee's will have sole responsibility for the importation of the drug product from the Company and for the costs of commercialization of Renazorb in the licensed territories. Both parties agreed to enter into a separate manufacturing and supply agreement whereby Unicycive will supply Lee's with Renazorb product. The Company has received an upfront payment of approximately $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.

The Company has evaluated the Agreement in accordance with FASB Topics 808 – Collaborative Arrangements and 606 -Revenue for Contracts from Customers. The Company first assessed whether the contractual arrangement is within the scope of ASC 808 which defines a collaborative arrangement as a contractual arrangement that involves a joint operating activity. Under ASC 606, the counterparty is considered a customer only if it is acquiring goods or services that are an output of the entity's "ordinary activities". The Agreement is consistent with the Company's current ongoing operations, which is an operating model adopted by many early-stage biotech companies. The license portion of the contract as well as the future potential transactions under a manufacturing and supply agreement both represent a vendor-customer relationship.

The Company does not believe that its promise to provide goods under a future manufacturing and supply agreement represents a material right to Lee's, and therefore the promise does not represent current performance obligation. The Company has concluded the agreement contains one performance obligation – the IP license.

ASC 606 indicates that constrained variable consideration should be included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration consisting of milestone payments and sales-based royalties may be received based on the completion of certain clinical, regulatory, and commercial activities. The Company has concluded that the future milestone payments should be excluded from the transaction price due to the uncertainty of achievement as of December 31, 2022. The Company will reassess this conclusion at each reporting date until the uncertainties are resolved.

For the sales-based royalty payments, guidance requires an entity to recognize revenue for a sales-based royalty promised in exchange for a license of intellectual property only when the later of 1) the subsequent sale or usage occurs, or 2) the performance obligation to which some or all the sales-based or usage-based royalty has been allocated has been satisfied or partially satisfied. The Company has concluded that the future sales-based royalties should be excluded from the transaction price as of December 31, 2022. The Company will reassess this conclusion at each reporting date.

The Company has concluded that at contract inception the total transaction price is the $1.0 million upfront fee.

The Company has concluded that the license of the Renazorb IP is functional IP as it contains all the necessary information for Lee's to develop for commercialization in the Territory. Unicycive's ongoing activities do not significantly affect the standalone functionality of the IP. In addition, the functionality of the IP is not expected to substantially change during the license period based on Unicycive's activities. The revenue should therefore be recognized at a point in time. This intellectual property was transferred to Lee's in July 2022, and the Company has recognized $1.0 million in the accompanying statements of operations as licensing revenue for the year ended December 31, 2022.

5. Balance Sheet Components

Prepaid expenses and other current assets as of December 31, 2021 and 2022 consisted of the following (in thousands):

	As of December 31, 2021	As of December 31, 2022
Prepaid directors and officers liability insurance premiums	$ 821	$ 476
Prepaid preclinical services	885	1,554
Other	126	159
Total	$ 1,832	$ 2,189

Property, plant and equipment as of December 31, 2021 and 2022 consisted of the following (in thousands):

	As of December 31, 2021	As of December 31, 2022
Leasehold improvements	$ 15	$ 15
Furniture and fixtures	14	14
Subtotal	29	29
Less accumulated depreciation	(1)	(7)
Net	$ 28	$ 22

Accounts payable as of December 31, 2021 and 2022 consisted of the following (in thousands):

	As of December 31, 2021	As of December 31, 2022
Trade accounts payable	$ 713	$ 846
Credit card liability	29	46
Total	$ 742	$ 892

Accrued liabilities as of December 31, 2021 and 2022 consisted of the following (in thousands):

	As of December 31, 2021	As of December 31, 2022
Accrued labor costs	$ 691	$ 1,487
Accrued drug development costs	369	228
Other	152	522
Total	$ 1,212	$ 2,237

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 is for two years, and there is an option to extend the lease for an additional year.

In accounting for the leases, the Company adopted ASC 842 Leases on January 1, 2019, which requires a lessee to record a right-of-use asset and a corresponding lease liability at the inception of the lease initially measured at the present value of the lease payments. The Company classified the lease as an operating lease and, at December 1, 2021, determined that the present value of the lease was approximately $318,000 using a discount rate of 8.0%. In accordance with ASC 842, the right-of-use asset will be amortized over the life of the underlying lease. The Company determined that the option to extend the lease for an additional year was not considered reasonably certain at December 31, 2021 or December 31, 2022. During the year ended December 31, 2022, the Company reflected amortization of right-of-use asset of approximately $154,000, resulting in a right of use asset balance of $152,000.

During the year ended December 31, 2022, the Company made cash payments on the lease of $170,000 towards the lease liabilities. As of December 31, 2022, the total lease liability was $155,000. ASC 842 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. Rent expense for the lease for the years ended December 31, 2021 and December 31, 2022 was approximately $14,000 and $173,000, respectively.

Maturities of the Company's lease liabilities are as follows (in thousands):

	Operating Lease
Year ending December 31, 2022	$ 161
Less imputed interest rate / present value discount	(6)
Present value of lease liability	155
Less current portion	(155)
Long term portion	$ -

7. Debt

Convertible Notes

In January through May 2021, the Company issued convertible notes (the "2021 Notes") in the aggregate principal amount of approximately $1,098,000. The 2021 Notes bear interest at a rate of 12% per annum, payable at maturity, and mature between January and May, 2022. The 2021 Notes shall automatically convert into shares of the Company's common stock upon the closing of a financing pursuant to which the Company receives gross proceeds of at least $0.5 million (a "Qualified Financing") or upon a change of control. The 2021 Notes shall convert into such numbers of shares of the Company's common stock equal to the conversion amount divided by the Conversion Price. "Conversion Price" means (i) in the event of a Qualified Financing, 70% of the price per share (or conversion price, as applicable) of common stock (or securities convertible into common stock, as applicable) sold in such financing or (ii) in the event of a change of control, the price per share reflected in such transaction.

The Company accounted for the 2021 Notes as stock-settled debt and was accreting the carrying amount of the 2021 Notes to the settlement amount through maturity.

In July through November 2020, the Company issued convertible notes (the "2020 Notes") in the aggregate principal amount of $1,290,000. The 2020 Notes bear interest at a rate of 12% per annum, payable at maturity, and mature between July and November, 2021. The 2020 Notes shall automatically convert into shares of the Company's common stock upon the closing of a financing pursuant to which the Company receives gross proceeds of at least $0.5 million (a "Qualified Financing") or upon a change of control. The 2020 Notes shall convert into such numbers of shares of the Company's common stock equal to the conversion amount divided by the Conversion Price. "Conversion Price" means (i) in the event of a Qualified Financing, 70% of the price per share (or conversion price, as applicable) of common stock (or securities convertible into common stock, as applicable) sold in such financing or (ii) in the event of a change of control, the price per share reflected in such transaction.

The Company accounted for the 2020 Notes as stock-settled debt and is accreting the carrying amount of the 2020 Notes to the settlement amount through maturity. As of December 31, 2020, unpaid and accrued interest of $0.1 million as well as debt discount accretion expense of approximately $0.2 million was included with the convertible notes on the balance sheet.

As a result of the completion of the Company's IPO on July 13, 2021, approximately $2.4 million of principal and $0.2 million of unpaid accrued interest related to the 2021 and 2020 Notes was converted into shares of common stock. Additionally the noteholders were granted warrants equal to 25% of the conversion shares issued. The conversion resulted in a loss of $0.4 million that is included as loss on debt conversion in the accompanying statements of operations for the year ended December 31, 2021.

Paycheck Protection Program Loan

On April 23, 2020, the Company entered into an $18,000 loan with Silicon Valley Bank pursuant to the Small Business Administration's ("SBA") Paycheck Protection Program ("PPP") as well as a $1,000 loan pursuant to the Economic Injury Disaster Assistance Program. The PPP loan proceeds are intended to be used for payroll over the eight-week period following the date of the loan. The loan terms provide that no principal or interest payments are due and interest will accrue at 1% per annum commencing on April 23, 2020 through October 23, 2020 (deferral period). Commencing one month after the deferral period and continuing monthly through the maturity of the loan on April 23, 2022, equal monthly payments of principal and interest are due. The Company classified the loans as a current liability, has applied for and received loan forgiveness in February 2021, and recorded a gain on extinguishment of debt in the statement of operations for the year ended December 31, 2021.

8. Related Party Transactions

Loan from Chief Executive Officer and Stockholder

The Company received advances from a stockholder of $248,000 during the year ended December 31, 2021. The Company repaid all amounts owed to the stockholder of $1.4 million during the year ended December 31, 2021.

Common Stock Purchase Agreement and Service Agreement with Globavir

On July 1, 2017, the Company entered into a Common Stock Purchase Agreement ("Stock Agreement") with Globavir. The Company's principal stockholder is also the principal stockholder in Globavir. The Stock Agreement provided for the distribution of 62,181 shares of the Company's common stock, valued at $0.013 per share, to Globavir's stockholders as payment for Globavir's services and shared costs rendered on behalf of the Company in 2017, which were issued in 2018.

On July 1, 2017, as amended on April 6, 2020, the Company entered into a Service Agreement with Globavir Biosciences, Inc. ("Globavir"), a related party (the "Service Agreement"). Globavir provides administrative and consulting services and shared office space and other costs in connection with the Company's drug development programs. The initial amended term of the Service Agreement expired on December 31, 2020, and the agreement automatically renews for successive one month periods after the initial termination date. Pursuant to the Service Agreement, the Company paid Globavir $50,000 per month through December 31, 2019 and $10,000 per month commencing on January 1, 2020. During the fourth quarter of 2021, after initially determining that future services under the Service Agreement were no longer required, the Company wrote off the $28,000 remaining prepaid balance due from Globavir as of December 31, 2021. During the year ended December 31, 2022, after determining that although a shared office space is no longer utilized, consulting services continued to be provided, the Company amended the Service Agreement to reflect the consulting services at a reduced service fee of $6,000 per month and a termination date of June 30, 2022.

9. 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. The Company currently has no pending claims or legal proceedings.

In September 2020, the Company signed an engagement letter (the "Benchmark Agreement") with The Benchmark Company LLC ("Benchmark") to act as the lead or managing underwriter in connection with the Company's planned initial public offering. In connection with this agreement the Company agreed to pay a nonaccountable expense allowance to Benchmark equal to 1.0% of the gross proceeds received in the Company's planned initial public offering. In addition to the non-accountable expense allowance, the Company has also agreed to pay or reimburse the underwriters for certain of the underwriters' out-of-pocket expenses relating to the offering, including all reasonable fees and expenses of the underwriters' outside legal counsel, and background checks, which shall not exceed in the aggregate $132,500.

In March 2021, the Benchmark Agreement was terminated. Concurrent with the termination, the Company signed an advisory services agreement pursuant to which the Company will pay Benchmark $150,000 upon the closing of the planned initial public offering, and Benchmark provided advisory services with respect to the public offering. The Company paid the $150,000 advisory fee in July 2021.

In December 2022, the Company signed an advisory services agreement with Maxim Group LLC ("Maxim") pursuant to which the Company will pay Maxim $100,000 upon the closing of a private placement of the Company's equity or equity-linked securities. Maxim provided advisory services with respect to a private placement securities purchase agreement with certain healthcare-focused institutional investors, which closed in March of 2023. The Company paid the $100,000 advisory fee in March 2023.

Indemnifications

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 $6,000 and $60,000 for the years ended December 31, 2021 and 2022, respectively.

10. Stockholders' (Deficit) Equity

Authorized Common Stock

The Company is authorized to issue up to 200,000,000 shares of common stock at par value of $0.001 per share.

Issuance of Common Stock and Warrants

During July 2021, as a result of its initial public offering, the Company issued 5,000,000 shares of common stock and 4,000,000 warrants to investors in exchange for cash at $5.00 per unit, consisting of $4.99 per share of common stock and $.0125 per four fifths of a warrant. The warrants have a 5-year term and an exercise price of $6.00 per warrant. The underwriters exercised their option to purchase an additional 600,000 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 736,773 shares of common stock. Additionally, convertible noteholders were granted a total of 184,193 common stock warrants with a 5-year term and with an exercise price of $6.00 per warrant.

The following table summarizes activity for warrants for the year ended December 31, 2022:

	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, 2021	4,784,193	6.00	4.54	-
Warrants granted	-	-	-	-
Warrants exercised	-	-	-	-
Outstanding, December 31, 2022	4,784,193	6.00	4.54	-

Voting Rights of Common Stock

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

Preferred Stock

As of December 31, 2021 and 2022, the Company had 10,000,000 shares of preferred stock authorized, par value of $0.001 per share and no shares of preferred stock were issued or outstanding.

11. 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 1,302,326 shares of common stock are reserved for issuance pursuant to the 2021 Plan. 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, 2021 and 2022, 674,176 and 389,676 shares of common stock, respectively, are available under the 2021 Plan.

In October 2019, the Company adopted the 2019 Stock Option Plan ("2019 Plan") which allowed for the granting of incentive stock options ("ISO"), non-qualified stock options ("NSO") to the employees, members of the board of directors and consultants of the Company. In 2019 and during the first seven months of 2020, the Company granted ISOs and NSOs to consultants and directors from the 2019 Plan. As of December 31, 2019, 232,558 shares were authorized for issuance and 75,581 shares were available for future grant under the 2019 Plan. On April 6, 2020 the Company increased the shares authorized for issuance to 348,837 shares total. On February 17, 2021, the Company increased the shares authorized for issuance to 1,767,442 shares total. As of July 15, 2021, no further awards may be issued under the 2019 Plan due to the adoption of the Company's 2021 Plan.

In 2018, the Company adopted the 2018 Equity Incentive Plan ("2018 Plan") which allowed for the granting of incentive stock options ("ISO"), non-qualified stock options ("NSO"), stock appreciation rights, restricted stock and restricted stock units to the employees, members of the board of directors and consultants of the Company. In 2018, the Company granted ISOs and NSOs to consultants and directors from this plan. As of December 31, 2020, 465,116 shares were authorized for issuance and 17,442 shares were available for future grant under the 2018 Plan. As of July 15, 2021, no further awards may be issued under the 2018 Plan due to the adoption of the Company's 2021 Plan.

The following table summarizes activity for stock options under all plans for the year ended December 31, 2022:

	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, 2021	1,211,068	$ 3.19	8.66	$ 321
Options granted	324,000	$ 0.75		
Options forfeited	(125,547)	$ 3.05		
Options exercised	(66,851)	$ 0.45		
Outstanding, December 31, 2022	1,342,670	$ 2.75	8.47	$ 52
Options vested and exercisable as of December 31, 2022	683,661	$ 3.14	7.87	$ 52

The grant date fair value of options granted during the year ended December 31, 2022 was $0.2 million.

As of December 31, 2022, the unrecognized compensation cost related to outstanding stock options was $1.1 million, which is expected to be recognized as expense over approximately 2.3 years.

During the year ended December 31, 2021, employees and consultants exercised a total of 383,721 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, 2022, 9,546 of the options remained unvested. Proceeds received related to the unvested options of approximately $31,000 at December 31, 2022 were included in accrued liabilities on the accompanying balance sheets and will be reclassified to equity as vesting occurs, provided the employees and consultants continue to provide services to the Company. Proceeds received related to the vested portion of options of $29,000 were reclassified to equity during the year ended December 31, 2022. The vested portion of the exercises was 374,168 shares at December 31, 2022.

During May 2022, the Company granted a consultant 10,000 restricted stock units with a grant date fair value of $7,200, resulting in a fair value per share of $0.72. Subject to the consultant's continued service, the restricted stock units shall vest upon the two-year anniversary of the date of grant. As of December 31, 2022, the unrecognized compensation cost related to the grant was approximately $5,000, which is expected to be recognized as expense over approximately 17 months.

During July 2021, the Company granted a director 26,738 restricted stock units with a grant date fair value of $100,000, resulting in a fair value per share of $3.74. The restricted stock units vested in July 2022.

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, 2021 and 2022 (in thousands):

	Year Ended December 31, 2021	Year Ended December 31, 2022
Research and development	$ 721	$ 664
General and administrative	245	383
Total stock-based compensation	$ 966	$ 1,047

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, 2022, the Company has never declared nor paid any cash dividends.

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, 2021 and 2022:

	Year Ended December 31, 2021	Year Ended December 31, 2022
Expected volatility	101.00 – 105.00%	101.00 – 105.00%
Risk-free interest rate	0.61 – 1.34%	2.90 – 3.96%
Dividend yield	-%	-%
Expected term	5.13 - 6.25 years	6.25 years

12. Income Taxes

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 years ended December 31, 2021 and 2022 is as follows:

	Year Ended December 31, 2021	Year Ended December 31, 2022
Income taxes (benefit) at statutory rates	21.00%	21.00%
State income tax (benefit), net of federal benefit	-	2.39%
Change in valuation allowance	(16.27)	(24.04)
Interest on convertible notes	(2.22)	-
Others	(2.51)	0.65
Effective income tax rate	-%	-%

For the years ended December 31, 2021 and 2022, the Company did not record a deferred income tax expense or benefit. Income tax expense has been nominal for the years ended December 31, 2021 and 2022.

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, 2021 and 2022 are shown below (in thousands):

	December 31, 2021	December 31, 2022
Deferred tax assets:		
Stock-based compensation	$ 226	$ 373
Net operating losses carryforwards	2,257	4,156
Depreciation and Amortization	468	428
Capitalized research	-	2,221
Accrued expenses	135	260
Gross deferred tax assets	3,086	7,438
Less: Valuation allowance	(3,086)	(7,438)
Deferred tax assets, net of valuation allowance	$ -	$ -

The valuation allowance increased by $4.4 million during the year ended December 31, 2022. 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's 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, 2022, the Company had available Federal and California net operating loss carryforwards of approximately $15.4 million and $13.1 million 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. These 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, 2022, the Company had research and development credit carryforwards of approximately $444,000 and $245,000 available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. These credits have been provided a full reserve 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, 2022 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.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted in response to the COVID-19 pandemic. The CARES Act, among other things, permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. In addition, the CARES Act allows NOLs incurred in 2018, 2019, and 2020 to be carried back to each of the five preceding taxable years to generate a refund of previously paid income taxes. Due to the Company's history of NOLs, the CARES Act did not have a material impact on the Company's financial statements.

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 Tax Cuts and Jobs Act ("TCJA") included a change in the treatment of research and development ("R&D") expenditures for tax purposes under Section 174. Effective for tax years beginning after December 31, 2021, specified R&D expenditures must undergo a 5-year amortization period for domestic spend and a 15-year amortization period for foreign spend. Prior to the effective date (2021 tax year and prior), taxpayers were able to immediately expense R&D costs under Section 174(a) or had the option to capitalize and amortize R&D expenditures over a 5-year recovery period under Section 174(b). The Company has evaluated the current legislation at this time and prepared the provision by following the treatment of R&D expenditures for tax purposes under Section 174.

The following table summarizes the changes to the Company's gross unrecognized tax benefits for the years ended December 31, 2021 and 2022 (in thousands):

	Year Ended December 31, 2021	Year Ended December 31, 2022
Beginning balance	$ 29	$ 101
Additions related to current year positions	72	589
Ending balance	$ 101	$ 690

As of December 31, 2021 and 2022, the total unrecognized tax benefit was approximately $101,000 and $690,000, respectively. The Company does not expect any material changes to the estimated amount of liability associated with its uncertain tax positions within the next 12 months. The Company's policy is to recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2022, the Company had no accrued interest and penalties related to uncertain tax positions.

The Company files U.S. 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.

13. Net loss per share

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

	Year Ended December 31, 2021	Year Ended December 31, 2022
Numerator:		
Net loss	$ (10,017)	$ (18,058)
Denominator:		
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	11,675,750	15,057,049
Net loss per share attributable to common stockholders, basic and diluted	$ (0.86)	$ (1.20)

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, 2021	Year Ended December 31, 2022
Options to purchase common stock	1,211,068	1,342,670
Warrants to purchase common stock	4,784,193	4,784,193
Total	5,995,261	6,126,863

14. Subsequent Events

On February 1, 2023, the Company entered into an exclusive license agreement with Lotus Pharmaceutical ("Lotus"), a leading global pharmaceutical company, for the development and commercialization of Renazorb® (lanthanum dioxycarbonate) in the Republic of Korea. Under the terms of the agreement, Lotus will be responsible for development, registration filing and approval of Renazorb in the Republic of Korea. In addition, Lotus will have sole responsibility for the importation of the drug product from Unicycive and for the costs of commercialization of Renazorb in the Republic of Korea. Unicycive received an upfront payment of $750,000, less applicable withholding taxes, and may receive up to $4.45 million in milestone payments and tiered royalties upon achievement of prespecified regulatory and commercial achievements.

The Company received advances from a stockholder of $210,000 during February, 2023. The Company repaid amounts owed to the stockholder of $210,000 plus accrued interest during March 2023.

On March 3, 2023, the Company signed a securities purchase agreement with certain healthcare-focused institutional investors that will provide up to $130 million in gross proceeds to Unicycive through a private placement that includes initial upfront funding of $30 million. The funding is being led by Vivo Capital with participation from RA Capital, BVF Partners, Logos Capital, and is supported by existing investors Nantahala Capital Partners and Rosalind Advisors Inc. In conjunction with the financing, Gaurav Aggarwal, M.D., Managing Director of Vivo Capital, will join the Unicycive Board of Directors.

Pursuant to the securities purchase agreement, the Company issued to institutional purchasers (i) $30 million in shares of the Company's Series A Convertible Preferred Stock and (ii) three tranches of warrants that are exercisable for convertible preferred stock as follows:

- The Tranche A warrants for an aggregate exercise price of approximately $25 million are exercisable until 21 days following the Company's announcement of receipt of FDA approval for Renazorb;
- The Tranche B warrants for an aggregate exercise price of approximately $25 million are exercisable until 21 days following the Company's announcement of receipt of TDAPA approval for Renazorb; and
- The Tranche C warrants for an aggregate exercise price of approximately $50 million are exercisable until 21 days following public disclosure of four quarters of commercial sales of Renazorb following receipt of TDAPA approval.

In addition, the Company issued (i) $190,000 in shares of the Company's Series A Convertible Preferred Stock and (ii) three tranches of warrants that are exercisable for convertible preferred stock to employees of the Company.

Shares of Series A Convertible Preferred Stock were issued at a price of $1,000.00 per share.

In addition, 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 Renazorb by the FDA if obtained, and the commencement of commercial sales.

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, 2022, 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, 2022, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective as we did not design or maintain an effective control environment commensurate with the financial reporting requirements. Specifically, we lack a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately while maintaining appropriate segregation of duties. Without such professionals, we did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries.

The lack of adequate staffing levels and expertise of unusual or infrequent transactions with complex or infrequently applied accounting topics resulted in the insufficient level of supervision, review and approval of certain information used to prepare our financial statements and the maintenance of effective controls to adequately monitor and review significant transactions for financial statement completeness and accuracy. These control deficiencies, although varying in severity, contributed to the material weakness in the control environment. If one or more material weaknesses persist or if we fail to establish and maintain effective internal control over financial reporting, our ability to accurately report our financial results could be adversely affected.

The above material weakness did not result in a material misstatement of our previously issued financial statements, however, it could result in a misstatement of our account balances or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

Management is taking steps to remediate the material weakness in our internal control over financial reporting. To address the issues, we plan to hire additional personnel. Specifically, management will:

- Increase the number of accounting personnel;
- Engage third party experts to assist management in completing a comprehensive risk assessment to identify, design and implement control activities; and
- Review and enhance business policies, procedures and related internal controls to standardize business processes.

We expect to complete the remediation by the end of 2023. We expect to incur additional costs to remediate this weakness, primarily personnel costs.

Management's 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, 2022, 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, 2022, our internal control over financial reporting was not effective due to a material weakness in our internal control over financial reporting as discussed above in our evaluation of disclosure controls.

The lack of adequate staffing levels and expertise of unusual or infrequent transactions with complex or infrequently applied accounting topics resulted in the insufficient level of supervision, review and approval of certain information used to prepare our financial statements and the maintenance of effective controls to adequately monitor and review significant transactions for financial statement completeness and accuracy. These control deficiencies, although varying in severity, contributed to the material weakness in the control environment. If one or more material weaknesses persist or if we fail to establish and maintain effective internal control over financial reporting, our ability to accurately report our financial results could be adversely affected.

In light of the material weakness, we performed additional analysis and other post-closing procedures to ensure the reliability of financial reporting and that our financial statements were prepared in accordance with U.S. GAAP. Accordingly, we believe that the financial statements included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented.

Management is taking steps to remediate the material weakness in our internal control over financial reporting. To address the issues, we plan to hire additional personnel. Specifically, management will:

- Increase the number of accounting personnel;
- Engage third party experts to assist management in completing a comprehensive risk assessment to identify, design and implement control activities; and
- Review and enhance business policies, procedures and related internal controls to standardize business processes.

We expect to complete the remediation by the end of 2023. We expect to incur additional costs to remediate this weakness, primarily personnel costs.

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 that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our 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 2023 (the "2023 Proxy Statement"), under the heading "Election of Directors."

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information contained in the 2023 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 2023 Proxy Statement under the headings "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 2023 Proxy Statement under the headings "Family Relationships and other Arrangements."

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference from the information contained in the 2023 Proxy Statement under the heading "Proposal 2: Ratification of the Appointment of Our Independent Registered Public Accounting Firm for Fiscal Year Ending December 31, 2023."

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
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	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
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 (incorporated by reference to Exhibit 4.4 to Form 10-K filed on March 31, 2022).
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)
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)
14.1	Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14.1 to Form 10-K filed on March 31, 2022).
23.1	Consent of Mayer Hoffman McCann 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.
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).

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, 2023

/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, 2023
/s/ John Townsend John Townsend	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2023
/s/ John Ryan, M.D., Ph.D. John Ryan, M.D., Ph.D.	Director	March 30, 2023
/s/ Sandeep Laumas, M.D. Sandeep Laumas, M.D.	Director	March 30, 2023
/s/ Brigitte Schiller, M.D. Brigitte Schiller, M.D.	Director	March 30, 2023
/s/ Gaurav Aggarwal, M.D. Gaurav Aggarwal, M.D.	Director	March 30, 2023