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, 2021

☐ 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 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 definition 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. ☐

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

The number of shares of common stock outstanding as of March 31, 2022 was14,996,534.

Documents Incorporated by Reference: None.

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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 current 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.
- We need significant additional financing to fund our operations and complete the development and, if approved, the commercialization of our product candidates. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- 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.

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.
- 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

- We are currently listed on The Nasdaq Capital Market. If we are unable to maintain listing of our securities on Nasdaq or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

- 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.

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 that we believe 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 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). 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 2020 and 2021 we have conducted preclinical studies with UNI 494.

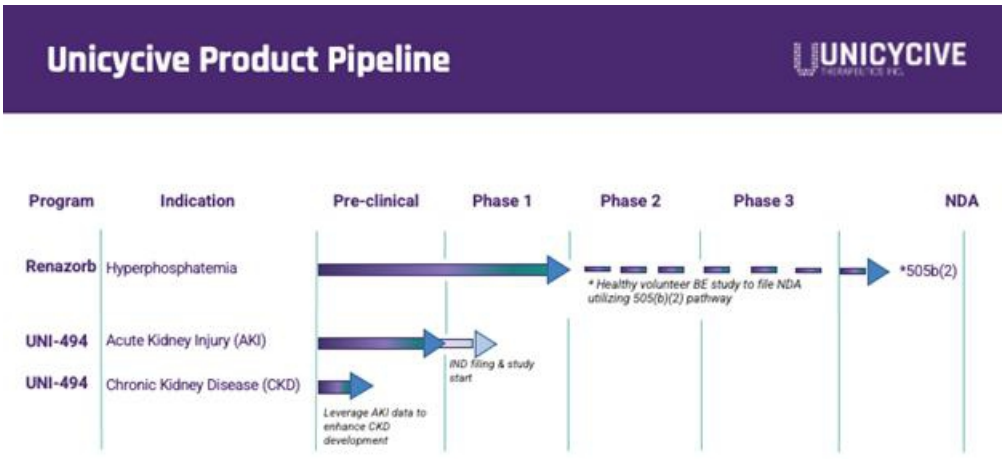
Chronic kidney disease (CKD) is the gradual loss of kidney function that can get worse over time leading to lasting damage. Our initial focus is on developing drugs and getting them approved in the US, and then to partner with global biopharmaceutical companies in the rest of the world. According to 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 have CKD stage 3-5, and around 500 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 in the US 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 U.S. patients and costs the healthcare system over $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, 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 our Company at an attractive price with limited upfront cost.

Pipeline

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



UNI-218 (Renazorb)

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 phosphate levels in the blood lead to cardiovascular complications and vascular calcification. According to Kidney Disease Improving Global Outcome (KDIGO) guidelines, hyperphosphatemia is defined as an abnormally high serum phosphate concentration >1.46 mmol/L. In healthy people, phosphate 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 phosphate in the blood. In CKD, hyperphosphatemia is caused by a chronic dysregulation of phosphates 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 phosphate concentration. Hyperphosphatemia is a major cause of morbidity in CKD patients, increasing the economic and clinical burden on patients and the health system.

According to Lederer in 2018, hyperphosphatemia occurs in at least 70% of patients with advanced (stage 5) CKD, which equates to approximately 500,000 patients. According to the 2019 National Chronic Kidney Disease Fact Sheet (Centers for Disease Control and Prevention, 2019), it is estimated that 15% of US adults (i.e. approximately 37 million people) have CKD. Furthermore, in a paper published by McCullough in 2019, the number of patients in the US with ESRD is increasing steadily and is projected to reach between 971,000 and 1,259,000 in 2030.

Current treatment of hyperphosphatemia

The treatment goal for patients with hyperphosphatemia is focused on controlling the level of phosphate in the body. Current Kidney Disease: Improving Global Outcomes, or KDIGO, guidelines recommend three main strategies for managing hyperphosphatemia: diet restrictions, phosphate binders, and dialysis, as shown in figure 1 below.

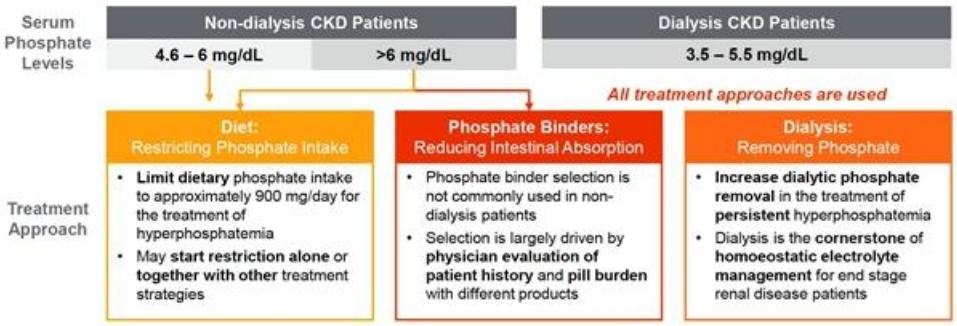


Figure 1: KDIGO guidelines recommend 3 main strategies.

While KDIGO guidelines support the treatment of hyperphosphatemia with phosphate binders in patients with CKD, they do not recommend one agent over another. Examples of different types of phosphate binders are shown in figure 2 below.

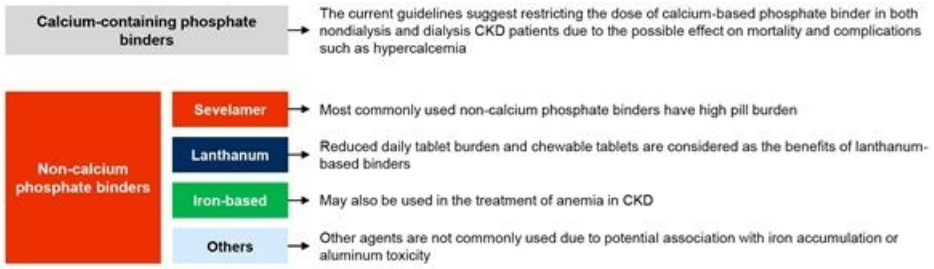


Figure 2: Phosphate Binders

This means that physicians prescribe their medication of choice, usually based on clinical and patient factors. In CKD patients on dialysis, hyperphosphatemia is most commonly treated with non-calcium phosphate binders.

The Unmet Medical Need for Treatment 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, large doses required to be effective, possible vascular calcification, unpalatable	Caltrate, Tums, PhosLo, Calphron
Sevelamer hydrochloride/carbonate	An anion exchange resin	Swallowed tablets	Calcium-free, lipid-lowering effect	Lower phosphate binding capacity, expensive, high pill burden, GI adverse effects	Renagel, Renvela
Lanthanum carbonate	Forms insoluble phosphate complexes in the gut	Chewable tablets	Low pill burden, high efficacy, works in wide range of pH, no negative changes on bone histology	Expensive, GI adverse effects, uncertain long-term 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	Velphoro
Ferric citrate	Forms insoluble phosphate complexes in the gut	Swallowed tablets	Also serves as a treatment for anemia in CKD	Expensive, high pill burden, GI adverse effects and cough	Auryxia
Aluminum hydroxide	Forms insoluble phosphate complexes in the gut	Swallowed tablets	Inexpensive, calcium-free, binds phosphate at wide range of pH	No safe dose established, significant adverse effects, requires regular monitoring of serum aluminum	AlternaGEL, Amphogel, Nephrox

Table 2: Adapted from Covic and Rastogi, 2013.

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 US 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 49 ± 19% of the total pill burden, with a median pill count of 9. Only 38% of patients in this study were adherent to their prescribed phosphate binder therapy and adherence decreased significantly with increased pill count also shown by Chiu, YW in 2009 publication.

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 that have high and rapid phosphate binding, alongside a reduced pill burden for better medication compliance.

Background on Renazorb

Renazorb (lanthanum dioxycarbonate) is a second-generation phosphate binding agent utilizing proprietary nanoparticle technology for the treatment of hyperphosphatemia in CKD patients. In September 2012 a Phase 1 single-center clinical trial was completed in the United States with Renazorb studying 32 healthy volunteers. Four sequential dose cohorts of 8 subjects each (6 active and 2 placebo) received Renazorb at 1500, 3000, 4500, or 6000 mg/day, taken orally in 3 divided doses within 15 min 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 doses of 3000 ($p=0.0004$), 4500 ($p<0.0001$), and 6000 ($p=0.0001$) mg/day. The mean increase in fecal phosphorus excretion was significant at doses of 1500 ($p=0.0358$), 3000 ($p=0.0006$), 4500 ($p=0.0026$), and 6000 ($p<0.0001$) mg/day. The doses resulted in no serious adverse events (SAEs) and all patients completed the study.

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.

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 phosphate levels.

In rat studies, Renazorb exhibited comparable binding kinetics compared to lanthanum carbonate (Fosrenol). This was evident from comparable reduction in the phosphate level in urine of rats following administration of equivalent doses of lanthanum through Renazorb (i.e. LDC or lanthanum dioxycarbonate) vs lanthanum dioxycarbonate tetrahydrate (i.e, LCTH or Fosrenol) (see Fig 3).

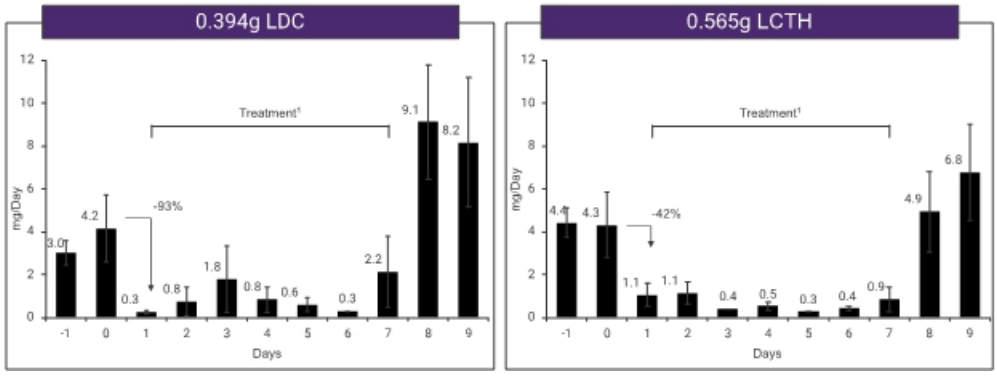


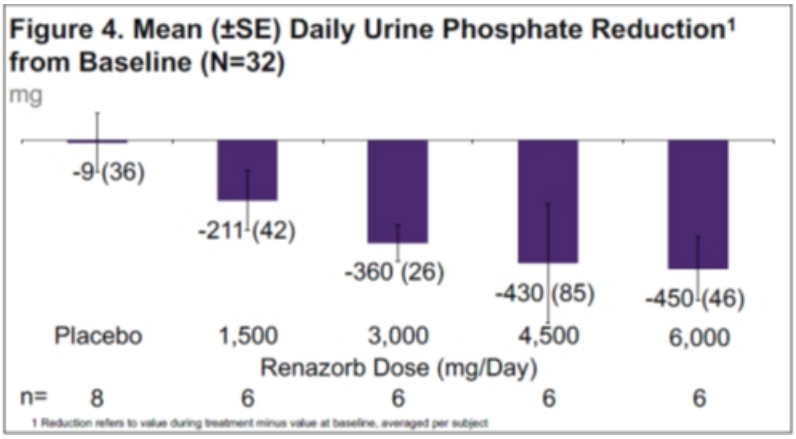
Figure 3: Urine phosphate levels in rats following comparable lanthanum dosing through Renazorb (LDC) or Fosrenol (LCTH)

Animal studies to evaluate the potential efficacy of Renazorb versus sevelamer hydrochloride (Renagel) in rats and dogs demonstrated significant lowering of phosphate levels in both urine and serum. In animal toxicology studies no unexpected toxicity was found and systemic absorption was extremely low that is consistent with Fosrenol.

The chemical design of Renazorb allows for smaller tablet size and fewer pills versus currently available phosphate binder alternatives, specifically with a dosing regimen of only one tablet per meal. The 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 was completed in the United States with Renazorb studying 32 healthy volunteers. Four sequential dose cohorts of 8 subjects each (6 actives and 2 placeboes) received Renazorb at 1500, 3000, 4500, or 6000 mg/day, taken orally in 3 divided doses within 15 min 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.



The mean increase in fecal phosphorus excretion was significant at 1500 (p=0.0358), 3000 (p=0.0006), 4500 (p=0.0026), and 6000 (p<0.0001) mg/day. The doses resulted in no serious adverse events (SAEs) and all patients completed the study.

Potential advantages of Renazorb

Renazorb is a phosphate binder for the treatment of hyperphosphatemia in patients with CKD 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 Fosrenol, Renagel/Renvela and Phoslo involve patients needing to take multiple and/or larger pills (on average, 9 pills/day), in addition to other, non-phosphate binder pills they sometimes need to take, resulting in poor adherence to the prescribed drug therapy (Figure 4 below). Lower molecular weight and no water of hydration with Renazorb as compared with Fosrenol allows Renazorb to be dosed in smaller mass. In this regard, we believe that the combined effect of smaller pill size, lower number of pills, and improved palatability with Renazorb versus currently available phosphate binders is likely to lead to improved patient compliance and more effective disease management.

Figure 4: Size comparisons of different phosphate binders

Market Potential

The worldwide market for hyperphosphatemia agents is estimated at ~$2.5 billion 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, based on the market data, the total US market makes up over $1 billion of the that total.

Based on the available data on overall efficacy, safety and compliance, we believe that Renazorb is well-positioned to become a product of choice in the multi-billion phosphate binder market.

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 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, 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.

Regulatory Strategy for Renazorb

Feedback from the FDA

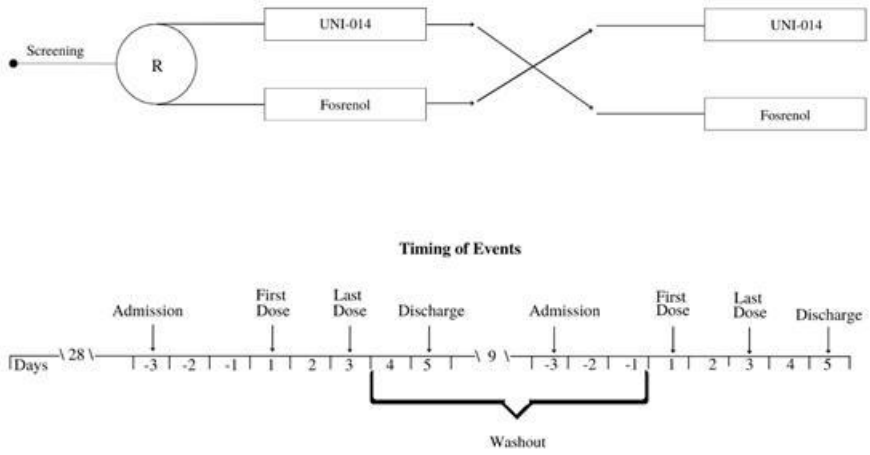
We received additional guidance on the regulatory pathway for Renazorb from the U.S. Food and Drug Administration (FDA) following a Type C meeting in March 2022, in which the Agency confirmed that a single clinical bioequivalence study in healthy volunteers, together with the previously agreed-upon 6-month 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 Agency on the clinical study design including the dose of Renazorb and Fosrenol, sample size and the primary endpoints of the bioequivalence study. The Agency confirmed that no additional clinical studies would be required for the NDA application.

BE Study Description

Based on guidance from the FDA, we are initiating a randomized, open label, two-way crossover BE study to establish pharmacodynamic bioequivalence between Renazorb

and Fosrenol. The study will enroll 32 individuals per treatment sequence for a total of 64 evaluable subjects. An adequate number of subjects will be screened and randomized in order to get 64 evaluable subjects into the study. The primary endpoint of the study is LS mean change in urinary phosphate excretion from baseline to the evaluation period. The study will consist of a screening period, 2 dosing periods, a washout period, and a follow-up period. The study design is presented in the diagram below:



We believe that our continued collaborative interactions with the FDA will serve us well to be able to file our NDA. Activities in support of each of the requirements recommended by FDA are underway. We intend to hold additional discussions with FDA during the second half of 2022 to confirm their concurrence with our dataset and NDA submission strategy with the goal to file NDA by the end of 2022 or early 2023.

UNI 494

Disease overview: acute kidney injury (AKI)

Acute kidney injury (AKI) — a loose collection of syndromes characterized by a sudden decrease in estimated glomerular filtration rate (eGFR) — is estimated to affect 2–3 people per 1,000 individuals in the United States as shown in a study published in The Journal of the American Medical Association (JAMA) by Kellum, JA in 2012. AKI is a serious condition characterized by a sudden decline in kidney function that can lead to kidney failure. AKI, and CKD can form a continuum (see figure below) whereby initial kidney injury can lead to persistent renal injury, eventually leading to CKD as shown in a 2017 study published by Chawla, LS in Nature Reviews Nephrology.

AKI is defined as an abrupt decrease in kidney function occurring over 7 days or less, whereas CKD is defined by the persistence of kidney disease for a period of >90 days. AKD describes acute or subacute damage and/or loss of kidney function for a duration of between 7 and 90 days after exposure to an AKI initiating event (Figure 6).

Figure 6: Adapted from Nature Review-Nephrology; Chawla LS et al. 2017

In the United States, approximately 1% of patients admitted to hospitals have AKI at the time of admission. The estimated incidence rate of AKI during hospitalization is 2-5%. AKI develops within 30 days postoperatively in approximately 1% of general surgery cases as shown in a paper by Kheterpal S in Journal Anesthesiology and arises in up to 67% of intensive care unit (ICU) patients as published in a paper by Goldberg R, 2008 in Advances in Chronic Kidney Disease. In recipients of solitary kidney transplants, 21% developed AKI within the first 6 months after transplantation as shown in a paper published by Panek R in 2016 in Clinical Transplantation.

In a prospective national cohort study that used an electronic AKI alert, the incidence of AKI was 577 per 100,000 population. Community-acquired AKI accounted for 49.3% of all incidence episodes, and 42% occurred in the context of pre-existing chronic kidney disease. The 90-day mortality rate was 25.6%, and 23.7% of episodes progressed to a higher AKI stage as published by Holmes J et al. in Clinical Journal of American Society of Nephrology in 2016.

The KDIGO criteria for AKI are shown below in Table 3. According to a study by Susantitaphong et al in 2013, using the KDIGO definition, an estimated 1 in 5 adults and 1 in 3 children worldwide experience AKI during a hospital episode of care.

Stage[a]	Serum creatinine level	Urine output
Diagnosis	• Increase of ≥0.3 mg/dl (26.5 µmol/l) within 48 h, or • Increase of ≥1.5-fold above baseline, known or assumed to have occurred within 7 days	• <0.5 ml/kg/h for 6 h
1	• ≥1.5–1.9 times baseline, or • >0.3 mg/dl (26.5 µmol/l) increase from baseline	• <0.5 ml/kg/h for 6–12 h
2	• ≥2.0–2.9 times baseline	• <0.5 ml/kg/h for ≥12 h
3	• ≥3.0 times baseline, or • Increase of serum creatinine to ≥4.0 mg/dl (353.6 µmol/l), or • RRT or • In patients aged <18 years, a decrease in eGFR to <35 ml/min/1.73 m²	• <0.3 ml/kg/h for ≥24 h or • Anuria for ≥12 h

Table 3: KDIGO criteria for AKI

The incidence of AKI varies among different patient populations and is shown below in Table 4. A 2018 study by Pavkov reported that the total number of hospitalizations with AKI increased from 953,926 in 2000 to 1,823,054 in 2006 and to 3,959,560 in 2014. Among persons with diabetes, AKI hospitalizations increased by 139%, from 23.1 to 55.3 per 1,000 persons and by 230% among persons without diabetes, from 3.5 to 11.7 per 1,000 persons (both p<0.001).

Hospital-acquired AKI is linked to 3 main areas: sepsis, procedures, and drug toxicity as shown below in Table 4.

Population	Age	Incidence (range)	RRT requirement (%)	Mortality (%)
Non-ICU hospitalized patients	Adult	<1 in 5 patients	<10	10–20
Critically ill patients	Adult	1 in 3 to 2 in 3 patients	5–11	NR
	Paediatric	1 in 4 patients (10–82%)	1–2	11
Patients undergoing cardiac surgery	Adult	1 in 5 patients (2–50%)	<5	10
	Paediatric	1 in 3 to 1 in 2 patients	NR	6
Patients with sepsis	Adult	1 in 20 to 1 in 2 patients	15	30–60

Table 4: Adapted from Hoste et al. 2018

Current treatment of acute kidney injury

Treatment options for AKI include continuous renal replacement therapy, renal transplant, and dialysis. In a majority of cases the damage to the kidney is irreversible, and the patient needs to have a renal transplant or be on dialysis for life. There are no approved medicines to treat AKI; there is therefore a high unmet medical need. If approved, UNI 494 (a patented pro-drug of nicorandil) has the potential to be a first-in-class drug for the treatment of AKI.

Background on nicorandil

Nicorandil, marketed in such products as Ikorel and Dancor, is indicated for the treatment of chronic stable angina pectoris. It is not currently approved in the United States but has been approved for use in Australia, the United Kingdom and most of Europe, and in India, Japan, South Korea, and Taiwan. Nicorandil is a dual-action potassium channel opener that relaxes vascular smooth muscle through membrane hyperpolarization via increased transmembrane potassium conductance and increased intracellular concentration of cyclic guanosine monophosphate (GMP). It is shown to dilate normal and stenotic coronary arteries and reduces both ventricular preload and afterload.

Nicorandil in acute kidney injury

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 replacement, which subsequently results in increased oxidative damage and cellular injury. The diagram below in Figure 7 (Che R, 2014) shows how mitochondrial dysfunction can lead to kidney disease.

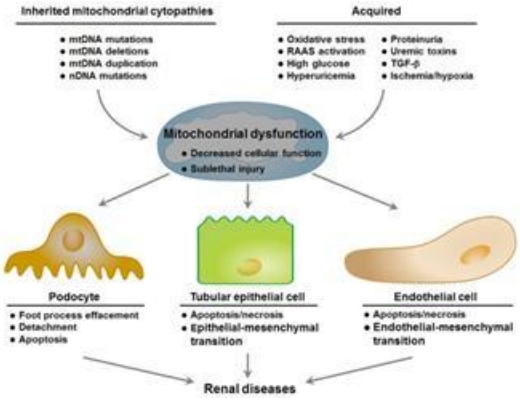
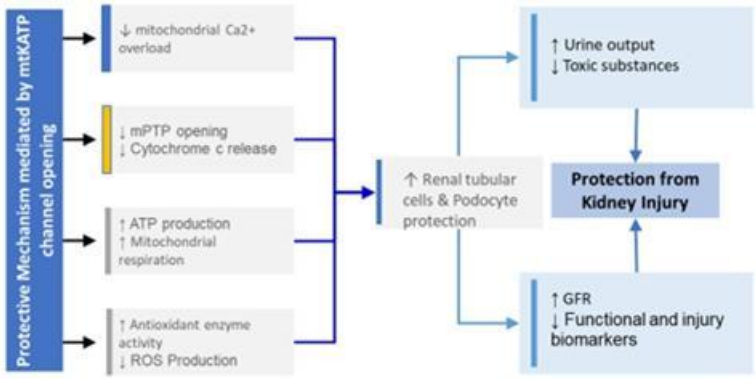


Figure 7: Che R, 2014: Mitochondria Dysfunction

Since mitochondrial dysfunction is an important factor in the pathogenesis of AKI, the mitochondria have emerged as a therapeutic target for treatment as published in a study by Ishimoto Y in 2016 in Journal Nephrology Dialysis Transplantation. In preclinical studies, nicorandil has been shown to improve mitochondrial function by blocking the opening of mitochondrial permeability transition pores (MPTP) and by stabilizing mitochondria against oxidative stress as published by Afzal, M in 2016 in Journal of Cardiovascular Pharmacology.

Figure 8 below shows the potential mechanisms of how nicorandil can improve mitochondrial function in renal disease.



Nicorandil has been reported to have a potential protective effect in the kidneys in nonclinical (Shiraishi 2014, Tamura 2012, Tanabe 2012) and human studies (Zhan 2018, Ma 2018). Further, no significant differences in pharmacokinetic parameters of nicorandil have been observed in patients with normal renal function as compared to those with impaired renal function (Molinaro 1992).

In animal studies, nicorandil has demonstrated efficacy in multiple standard models of kidney disease (see Table 5). 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:

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 5: Efficacy of nicorandil in standard models of kidney disease

Limitations of Nicorandil

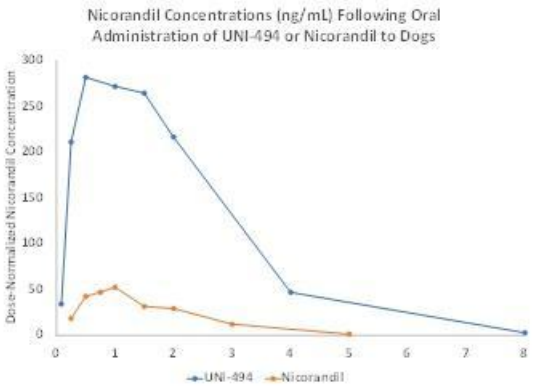
Despite these promising results, development of nicorandil for use in acute kidney injury has not been successfully pursued to date. Nicorandil possesses at least two features that may limit its use in this clinical setting. First, nicorandil has a short half-life in humans of approximately 1 hour, which results in the need to dose nicorandil multiple times per day to achieve sustained blood levels.

Second, nicorandil is well tolerated by most patients, with less than 10% of patients reporting side-effects after 30 days of treatment, and roughly 70% remaining on nicorandil at one year. Similar to nitrates, headache is the most common side effect to nicorandil, occurring in roughly one third of patients. Other relatively common side effects are: dizziness, flushing, malaise and gastro-intestinal upset. However, 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. 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 is a patented pro-drug that was 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 US. 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.

In October 2020, we completed 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 4 times greater systemic exposure to nicorandil compared with literature data on equimolar doses of nicorandil itself.



We have selected rat and dog as the most suitable species for the GLP toxicology program for UNI 494, which we plan to commence in 2022.

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 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 New Drug Application 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.

Clinical trials for UNI 494 in AKI

UNI 494 is currently in preclinical development. We plan to conduct repeat-dose animal toxicology studies and other IND-enabling preclinical studies in 2022 prior to initiating clinical development of 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 mechanism of action of the drug, we are in discussions with key opinion leaders (KOLs) to identify t 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.

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 US 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 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 AKI, we believe a conservative market estimate is approximately $3 billion in the US 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.

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 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 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 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 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 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.clinicaltrials.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 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 ANDAs for generic versions of listed drugs. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the 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, are entitled to a seven-year data exclusivity period.

Pricing and Reimbursement

Successful commercialization of our products depends, in part, on the availability of governmental and third-party payor reimbursement for the cost of our products. Government authorities and third-party payors increasingly are challenging the price of medical products and services. On the government side, there is a heightened focus, at both the federal and state levels, on decreasing costs and reimbursement rates for Medicaid, Medicare and other government insurance programs. This has led to an increase in federal and state legislative initiatives related to drug prices, which could significantly influence the purchase of pharmaceutical products, resulting in lower prices and changes in product demand. If enacted, these changes could lead to reduced payments to pharmaceutical manufacturers. Many states have also created preferred drug lists and include drugs on those lists only when the manufacturers agree to pay a supplemental rebate. If our current products or future product candidates are not included on these preferred drug lists, physicians may not be inclined to prescribe them to their Medicaid patients, thereby diminishing the potential market for our products.

In addition, third-party payors have been imposing additional requirements and restrictions on coverage and limiting reimbursement levels for pharmaceutical products. Third-party payors may require manufacturers to provide them with predetermined discounts from list prices and limit coverage to specific pharmaceutical products on an approved list, or formulary, which might not include all of the FDA-approved pharmaceutical products for particular indications. Third-party payors may challenge the price and examine the medical necessity and cost-effectiveness of pharmaceutical products in addition to their safety and efficacy. Manufacturers may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of pharmaceutical products in addition to the costs required to obtain the FDA approvals. Adequate third-party reimbursement may not be available to enable manufacturers to maintain price levels sufficient to realize an appropriate return on their investment in drug development.

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 $11,181 to $22,363 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 of up to $15,270 for each wrongful act, assessment of three times the amount claimed for each item or service 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.

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 $165,786 per year (or up to an aggregate of $1.105 million per year 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 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 31, 2022, we had 9 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, 2020 and 2021 was $2.3 million and $10.0 million, and our accumulated deficit as of December 31, 2021 was $15.9 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, 2020 and 2021, we had cash of less than $1,000 and $16.6 million, respectively. We expect our existing cash as of December 31, 2021 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.

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 fail to receive marketing approval for many reasons, including among others:

- the FDA may disagree with the design or implementation of our clinical trials;
- the FDA could determine that we cannot rely on 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 Section 505(b)(2) 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 significant 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 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 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 ("COVID-19") has evolved into a global pandemic. The coronavirus has spread to many regions of the world. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

As a result of the continuing spread of COVID-19, our business operations could be delayed or interrupted. Currently, we operate virtually, i.e., our program activities are and will continue to be carried out, on our behalf, by competent contract research organizations (CROs) with expertise in pre-clinical, clinical and/or chemistry and manufacturing areas. 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. Due to shelter-in-place/stay-at-home orders and other government restrictions, our employees conducting research and development or manufacturing activities at external vendor locations across the globe may not be able to access their laboratory or manufacturing space which may result in our core activities being significantly limited or curtailed, possibly for an extended period of time.

Moreover, our clinical trials may be affected by the COVID-19 pandemic. 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 the COVID-19 pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to execute clinical trial protocols per the expected timelines. The new mutations of the virus may also make it harder for us to predict the exact impact (if any) on the progression of COVID-19 on our development programs. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if the spread of the COVID-19 pandemic continues and our operations are adversely impacted, we risk a delay, default and/or nonperformance under existing agreements which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance.

Infections and deaths related to the pandemic may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review or review by other regulatory agencies and/or approval with respect to, our clinical trials. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

The spread of the coronavirus, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, 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, 2021, we had 8 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, 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.

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 current 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, 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.

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.

Our directors, executive officers and principal stockholders, and their respective affiliates, beneficially own approximately 41% 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.

Future sales and issuances of our common stock could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations, including increased marketing, hiring new personnel, commercializing our product, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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.

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. Any return to stockholders will therefore be limited to the increase, if any, of our share price.

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 $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (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. 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, 2020 and 2021, 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.

Use of Proceeds from Initial Public Offering

On July 15, 2021, we closed the initial public offering ("IPO") of our common stock pursuant to which we issued and sold 5,000,000 units at an initial public offering price of $5.00 per Unit. All of the shares of common stock issued and sold in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-256367), which was declared effective by the SEC on July 12, 2021. We received net proceeds of approximately $22.3 million, after deducting underwriting discounts and commissions and offering expenses borne by us. None of the expenses incurred by us were direct or indirect payments to any of (i) our directors or officers or their associates, (ii) persons owning 10% or more of our common stock, or (iii) our affiliates. There has been no material change in the planned use of proceeds from our initial as described in our final prospectus filed with the SEC on July 14, 2021 pursuant to Rule 424(b)(4). Roth Capital Partners acted as sole book-running manager for the offering. The offering commenced on July 13, 2021 and did not terminate before all securities registered in the registration statement were sold.

Stockholders

As of March 4, 2022, there were 977 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 have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

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 certain medical conditions. Currently, two of our programs are focused on kidney disease that we believe 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 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 to partner with 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 in the US 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 $2.3 million and $10.0 million for the years ended December 31, 2020 and 2021. As of December 31, 2021, we had an accumulated deficit of $15.9 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. In addition, we expect to incur additional costs associated with operating as a public company.

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

Between January 1, 2021 and May 19, 2021, we issued a series of convertible promissory notes in the aggregate principal amount of $1.1 million. These notes bear interest at a rate of 12% per annum and mature on the one year anniversary of their respective dates of issuance. These notes automatically converted into common stock upon consummation of our IPO at 70% of the public offering price per unit.

As a result of its 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 offering expenses.

On July 15, 2021, in connection with the completion of the Company's IPO, all outstanding convertible notes, including principal and accrued interest, were automatically converted into shares of common stock. The conversion was calculated based on 70% of the IPO price per unit and resulted in the issuance of 736,773 shares of common stock and 184,193 warrants to purchase additional shares of common stock.

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

Operating Expenses

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, 2020 and 2021 (in thousands)

	Years Ended December 31,			
	2020	2021	Change	% Change
Operating expenses:				
Research and development	$ 1,015	$ 6,080	$ 5,065	499%
General and administrative	1,005	2,897	1,892	188%
Total operating expenses	2,020	8,977	6,957	344%
Loss from operations	(2,020)	(8,977)	(6,957)	344%
Other income (expenses):				
Interest expense	(244)	(628)	(384)	157%
Loss on debt conversion	-	(431)	(431)	100%
Gain on extinguishment of debt	-	19	19	100%
Total other income (expenses)	(244)	(1,040)	(796)	326%
Net loss	$ (2,264)	$ (10,017)	$ (7,753)	342%

Research and Development Expenses

Research and development expenses increased by approximately $5.1 million, or 499%, from $1.0 million for the year ended December 31, 2020 to $6.1 million for the year ended December 31, 2021. The increase in research and development expenses was primarily due to a $2.1 million increase in non-cash expense from the issuance of common stock pursuant to the anti-dilution clause in the purchase of in process research and development technology from Spectrum Pharmaceuticals, Inc. Non-cash stock compensation costs increased $547,000. In addition, development costs increased $1.4 million due to product formulation and preclinical study services in the current period. New employee hires increased labor costs $868,000, and consulting and other costs increased $178,000 from the prior period.

General and Administrative Expenses

General and administrative expenses increased by approximately $1.9 million, or 188%, from $1.0 million for the year ended December 31, 2020 to $2.9 million for the year ended December 31, 2021 primarily due to an increase of $729,000 in insurance expense for directors and officers. Labor costs increased $410,000 due to hiring of new employees. Consulting and professional services costs increased $401,000. Stock compensation increased $187,000, and rent, travel, supplies and other costs increased $165,000.

Other Income (Expenses)

Other income (expenses) increased by approximately $796,000, or 326% from $244,000 for the year ended December 31, 2020 to approximately $1.0 million for the year ended December 31, 2021. The increase was due primarily to increased interest expense incurred on our convertible notes of $384,000 as well as conversion to equity of our outstanding convertible notes as a result of our IPO which resulted in a non-cash loss on debt conversion of $431,000. The increase was partially offset by a gain on extinguishment of our 2020 Paycheck Protection Plan loan of $19,000.

Liquidity and Capital Resources

Sources of Liquidity

Since our formation through December 31, 2021, 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 2020, we raised additional funds through private placements by issuing common stock for $141,000 and by issuing $1.3 million in convertible notes to investors. During the year ended December 31, 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 intend to use 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 Funding Requirements

We have incurred net losses since our inception. For the year ended December 31, 2021, we had a net loss of $10.0 million, and we expect to incur substantial additional losses in future periods. As of December 31, 2021, we had an accumulated deficit of $15.9 million.

We expect to continue incurring losses for the foreseeable 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 the Company's current level of expenditures, after receiving the net proceeds of $22.3 million on July 15, 2021 as a result of the Company's IPO and given the Company's cash balance of approximately $16.6 million as of December 31, 2021, the Company believes that it has 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 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 on July 1, 2017, as amended on April 6, 2020 ("Service Agreement"), with Globavir Biosciences, Inc. ("Globavir"). Our Chief Executive Officer is also the Chief Executive Officer of Globavir. Pursuant to the Service Agreement, we receive administrative, consulting services, shared office space and other services in connection with our 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, we paid Globavir $50,000 per month through December 31, 2019 and $10,000 per month commencing on January 1, 2020. As of December 31, 2020, $9,000 was payable to Globavir for service fees. During the fourth quarter of 2021, we determined that future services under the Service Agreement were no longer required, and we wrote off the $28,000 remaining prepaid balance due from Globavir as of December 31, 2021. Service fee expenses were $120,000 and $148,000 for the years ended December 31, 2020 and 2021, respectively, and were recorded as general and administrative expenses in the statements of operations.

Convertible Notes

In January through May 2021, we issued convertible notes (the "2021 Notes") in the aggregate principal amount of $1.1 million. 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 $1.3 million. 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 were 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 the completion of our IPO on July 15, 2021, approximately $2.4 million 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.

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,	
	2020	**2021**
Net cash (used in) provided by:		
Operating activities	$ (1,459)	$ (5,767)
Investing activities	-	(29)
Financing activities	1,444	22,375
Net (decrease) increase in cash	$ (15)	$ 16,579

Cash Flows from Operating Activities

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.

Net cash used in operating activities was $1.5 million for the year ended December 31, 2020. Cash used in operating activities resulted from a net loss of $2.3 million primarily driven by the use of funds in our operations to develop our product candidates as well as the deferral of the chief executive officer compensation of $396,000.

Cash Flows from Investing Activities

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. There were no comparable fixed asset purchases during the prior year.

Cash Flows from Financing Activities

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 IPO, 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 $119,000 in proceeds from the exercise of options. Net repayments on loans from our chief executive officer offset the cash inflows by $1.1 million.

Net cash provided by financing activities was $1.4 million for the year ended December 31, 2020 and was primarily driven by proceeds received for convertible notes.

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 research and development accruals, stock-based compensation and common stock valuations. There have been no material changes to our critical accounting policies and estimates during the year ended December 31, 2021 from those used for the year ended December 31, 2020. The below policies are listed to provide a list of our policies for the most significant critical policies.

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. We estimate progress achieved on material third party research and development contracts through a combination of direct and indirect interaction with the service providers as well as internal management assessment. 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, risk-free interest rate, and the estimated fair value of the underlying common stock on the date of grant.

Common Stock Valuations

Prior to our IPO, we were required to periodically estimate the fair value of common stock, with the assistance of an independent third-party valuation expert, when issuing stock options and computing their estimated stock-based compensation expense. 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, we considered, among other things, contemporaneous transactions involving the sale of our common stock to unrelated third parties, the lack of marketability of our common stock and the market performance of comparable publicly traded companies.

Subsequent to our IPO, we determine the fair value of our common stock from closing prices as quoted on the NASDAQ exchange.

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 $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our IPO; (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.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under SEC rules.

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, 2021 and 2020, and the related statements of operations, stockholders' (deficit) equity, and cash flows for each of the two years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, 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 31, 2022

Unicycive Therapeutics, Inc.

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

	As of December 31, 2020	As of December 31, 2021
Assets		
Current assets:		
Cash	$ -	$ 16,579
Deferred offering costs	200	-
Prepaid expenses and other current assets	4	1,832
Total current assets	204	18,411

Right of use asset, net	-	305
Property, plant and equipment, net	-	28
Total assets	$ 204	$ 18,744
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 184	$ 742
Related party service fee payable	9	-
Accrued liabilities	168	1,212
Convertible notes	1,528	-
Loan from stockholder	967	-
Operating lease liability - current	-	151
Government loan	19	-
Total current liabilities	2,875	2,105
Operating lease liability – long term	-	155
Total liabilities	2,875	2,260
Commitments and contingencies (Note 8)		
Stockholders' (deficit) equity:		
Preferred stock: $0.001 par value per share—10,000,000 shares authorized at December 31, 2020 and 2021;no shares issued and outstanding at December 31, 2020 and 2021	$ -	$ -
Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2020 and 2021;8,514,070 shares issued and outstanding at December 31, 2020, and 14,996,534 shares issued and outstanding at December 31, 2021	9	15
Additional paid-in capital	3,242	32,408
Accumulated deficit	(5,922)	(15,939)
Total stockholders' (deficit) equity	(2,671)	16,484
Total liabilities and stockholders' (deficit) equity	$ 204	$ 18,744

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, 2020	Year Ended December 31, 2021
Operating expenses:		
Research and development	$ 1,015	$ 6,080
General and administrative	1,005	2,897
Total operating expenses	2,020	8,977
Loss from operations	(2,020)	(8,977)
Other expenses:		
Interest expense	(244)	(628)
Loss on debt conversion	-	(431)
Gain on extinguishment of debt	-	19
Total other expenses	(244)	(1,040)
Net loss	$ (2,264)	$ (10,017)
Net loss per share, basic and diluted	$ (0.27)	$ (0.86)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	8,499,687	11,675,750

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, 2019	-	$ -	8,456,179	$ 8	$ 2,766	$ (3,658)	$ (884)
Net loss	-	-	-	-	-	(2,264)	(2,264)
Issuance of common stock for cash	-	-	33,263	1	141	-	142
Issuance of common stock for anti-dilution clause	-	-	24,628	-	104	-	104

Stock-based compensation expense	-	-	-	-	231	-	231
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

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.

Statements of Cash Flows
(in thousands)

	Year Ended December 31, 2020	Year Ended December 31, 2021
Cash flows from operating activities		
Net loss	$ (2,264)	$ (10,017)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	-	1
R&D expense for issuance of common stock for anti-dilution clause	104	2,191
Stock-based compensation expense	232	966
Convertible debt discount amortization	186	488
Amortization of operating lease right of use asset	-	12
Convertible debt non-cash interest	53	139
Gain on extinguishment of debt	-	(19)
Deferred compensation to CEO	396	146
Loss on debt conversion	-	431
Changes in assets and liabilities:		
Prepaid expense and other current assets	1	(1,325)
Accounts payable and accrued liabilities	(68)	1,241
Operating lease liability	-	(12)
Related party service fee payable	(99)	(9)
Net cash used in operating activities	(1,459)	(5,767)
Cash flows from investing activities		
Purchases of property, plant and equipment	-	(29)
Net cash used in investing activities	-	(29)
Cash flows from financing activities		
Net proceeds from initial public offering	-	22,271
Issuance of common stock for cash	141	-
Proceeds from loan from stockholder	271	248
Proceeds from convertible notes	1,290	1,098
Repayment of loan from stockholder	(160)	(1,361)
Deferred offering costs	(117)	-
Proceeds from exercise of options	-	119
Proceeds from government loan	19	-
Net cash provided by financing activities	1,444	22,375
Net (decrease) increase in cash	(15)	16,579
Cash at the beginning of the period	15	-
Cash at the end of the period	$ -	$ 16,579
Supplemental cash flow information		
Deferred offering costs included in accrued liabilities	$ 82	$ -
Deferred preclinical charges included in prepaid expenses and other current assets	$ -	$ 503
Cash paid for income taxes	$ 1	$ -

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 Nicorandil 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. The Company has not generated revenue to date.

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 for the foreseeable 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, 2020 and 2021, the Company had an accumulated deficit of $5.9 million and $15.9 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 intends to use 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.

The Company expects to continue incurring losses for the foreseeable 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 addition, the Company received approximately $22.3 million in net proceeds from its IPO. 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 given the Company's cash balance of $16.6 million as of December 31, 2021, the Company believes that it has 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.

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 progress estimates for material third party research and development contracts, stock-based compensation and fair value of the Company's common stock prior to the Company's IPO. 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 ongoing 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.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting and other fees and costs relating to the Company's IPO were capitalized and recorded as a current asset on the balance sheet. There were $0.2 million of deferred offering costs capitalized as of December 31, 2020. As of December 31, all previously deferred offering costs, totaling approximately $0.9 million, were netted against the proceeds received upon the closing of the IPO, which occurred on July 15, 2021.

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, 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, 2020 and 2021 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, and the account balance may at times exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institution in which the cash is held.

Prepaid Expenses

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

Research and Development Expenses

Substantially all 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 and related progress estimates for those activities, 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 7).

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 of the Company's underlying common stock on the date of grant.

Common Stock Valuations

Prior to the Company's IPO, the fair value of common stock was estimated with the assistance of an independent third-party valuation expert when issuing stock options and computing their estimated stock-based compensation expense. 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 common stock to unrelated third parties, the lack of marketability of the common stock and the market performance of comparable publicly traded companies.

Subsequent to our IPO, the Company determines the fair value of common stock from closing prices as quoted on the NASDAQ exchange.

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.

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 is currently evaluating the impact this guidance will have on its 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 certain 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, 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.

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. As part of the anti-dilution clause, the Company issued 149,762 and 105,897 shares of common stock during the years ended December 31, 2019 and 2020, respectively. The Company recognized $145,000 and $104,000 for the years ended December 31, 2019 and 2020, respectively, as research and development expenses as cost to issue those shares. On July 13, 2021, the Company's IPO 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 represents 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.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.

On February 8, 2021, the Company entered into a Master Services Agreement (the "Renazorb Development Agreement") with Ascent Development Services, Inc. ("Ascent") pursuant to which Ascent will provide strategic services related to the development of Renazorb or other investigational products (the "Compounds") for clinical use and regulatory approval in Japan and other Asian countries. The Renazorb Development Agreement anticipates services to be provided by Ascent will include market research, facilitation of informal and formal meetings with Japan's Pharmaceutical and Medical Devices Agency ("PMDA"), management of contract research organizations and clinical trials, and government applications and regulatory filings related to the Asian development of the Compounds. Unicycive will supply the Compounds or other materials necessary for Ascent to perform the development services. The initial Statement of Work ("SOW") under the Renazorb Development Agreement encompasses the development of clinical strategy as well as both informal and formal meetings with the PMDA. The budget for the initial SOW is approximately 24,000,000 Japanese Yen, and an upfront payment of approximately $87,000, was paid to Ascent upon the execution of the Renazorb Development Agreement. Deliverables for the initial SOW were completed by December 31, 2021.

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 budget for the initial study, which will also include clinical pharmacology, translational sciences, and bioanalytical services, is approximately $1.9 million, and related payments totaling approximately $379,000 have been paid to Syneos during the year ended December 31, 2021.

4. Balance Sheet Components

Prepaid expenses and other current assets as of December 31, 2020 and 2021 consisted of the following (in thousands):

	As of December 31, 2020	As of December 31, 2021
Prepaid directors and officers liability insurance premiums	$ -	$ 821
Prepaid preclinical services	-	885
Other	4	126
Total	$ 4	$ 1,832

Property, plant and equipment as of December 31, 2020 and 2021 consisted of the following (in thousands):

	As of December 31, 2020	As of December 31, 2021
Leasehold improvements	$ -	$ 15
Furniture and fixtures	-	14
Subtotal	-	29
Less accumulated depreciation	-	(1)
Net	$ -	$ 28

Accounts payable as of December 31, 2020 and 2021 consisted of the following (in thousands):

	As of December 31, 2020	As of December 31, 2021
Trade accounts payable	$ 183	$ 713
Credit card liability	1	29
Total	$ 184	$ 742

Accrued liabilities as of December 31, 2020 and 2021 consisted of the following (in thousands):

	As of December 31, 2020	As of December 31, 2021
Accrued labor costs	$ -	$ 691

Accrued drug development costs	-	369
Other	168	152
Total	$ 168	$ 1,212

5. 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. During the year ended December 31, 2021, the Company reflected amortization of right-of-use asset of approximately $12,000, resulting in a right of use asset balance of $305,000.

During the year ended December 31, 2021, the Company made cash payments on the lease of $14,000 towards the lease liabilities. As of December 31, 2021, the total lease liability was $306,000. 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 year ended December 31, 2021 was approximately $14,000.

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

	Operating Lease
Year ending December 31, 2022	$ 170
Year ending December 31, 2023	161
Total lease payments	331
Less imputed interest rate / present value discount	(25)
Present value of lease liability	306
Less current portion	(151)
Long term portion	$ 155

6. Debt

Convertible Notes

In January through May 2021, the Company issued convertible notes (the "2021 Notes") in the aggregate principal amount of approximately $3.1 million. 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 $500,000 (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 has 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 $1.3 million. 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 $500,000 (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 has 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 $53,000 as well as debt discount accretion expense of approximately $186,000 was included with the convertible notes on the balance sheet.

As a result of the completion of the Company's IPO on July 15, 2021, approximately $2.4 million of principal and $191,000 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 $431,000 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.

7. 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 amounts owed to the stockholder of $1.4 million during the year ended December 31, 2021. As of December 31, 2020 and 2021, the current liability loan from a stockholder was approximately $967,000 and $0, respectively.

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. As of December 31, 2020, $9,000 was payable to Globavir for service fees. During the fourth quarter of 2021, after 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. Service fee expenses were $120,000 and $148,000 for the years ended December 31, 2020 and 2021, respectively, and were recorded as general and administrative expenses in the statements of operations.

8. 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 IPO. 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 IPO. 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 IPO, and Benchmark provided advisory services with respect to the public offering. The Company paid the $150,000 advisory fee in July 2021.

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 401K Plan which covers all eligible employees of the Company (the "401K Plan"). Employer matching contributions are immediately 100% vested. The Company's 401K 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 401K Plan totaled approximately $0 and $6,000 for the years ended December 31, 2020 and 2021, respectively.

9. 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 IPO, 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 IPO, the Company's outstanding convertible notes and unpaid accrued interest were converted into 736,773 shares of common stock. Additionally, in accordance with the original terms of the warrant agreements 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, 2021:

	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, 2020	-	-	-	-
Warrants granted	4,784,193	6.00	4.54	-
Warrants exercised	-	-	-	-
Outstanding, December 31, 2021	4,784,193	6.00	4.54	-

During July 2021, 438,374 shares of common stock were allocated to Spectrum Pharmaceuticals, Inc. in accordance with the anti-dilution provisions of the Company's Assignment and Asset Purchase Agreement with Spectrum.

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, 2021, 76,397 of the options remained unvested. Proceeds received related to the unvested options of $60,000 at December 31, 2021 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. The vested portion of the exercises was 307,317 shares at December 31, 2021.

During the year ended December 31, 2020, the Company issued33,263 shares to investors in exchange for cash at $4.21 per share and 24,627 shares to Spectrum following its anti-dilution provision (Note 3).

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, 2020 and 2021, the Company had10,000,000 shares of preferred stock authorized, par value of $0.001 per share and no shares of preferred stock were issued or outstanding.

10. 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.

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 and75,581 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 and17,442 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, 2021:

	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, 2020	786,047	$ 1.42	8.28	$ 2,201
Options granted	760,245	$ 3.82		
Options forfeited	(27,907)	$ 3.27		
Options exercised	(307,317)	$ 0.19		
Outstanding, December 31, 2021	1,211,068	$ 3.19	8.66	$ 321
Options vested and exercisable as of December 31, 2021	301,862	$ 3.19	7.94	$ 182

The grant date fair value of options granted during the year ended December 31, 2021 was $2.1 million.

As of December 31, 2021, the unrecognized compensation cost related to outstanding stock options was $2.0 million, which is expected to be recognized as expense over approximately 2.4 years.

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. Subject to the director's continued service, the restricted stock units shall vest upon the one-year anniversary of the date of grant. As of December 31, 2021, the unrecognized compensation cost related to outstanding restricted stock units was approximately $54,000, which is expected to be recognized as expense over approximately 7 months.

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, 2020 and 2021 (in thousands):

	Year Ended December 31, 2020	Year Ended December 31, 2021
Research and development	$ 174	$ 721
General and administrative	58	245
Total stock-based compensation	$ 232	$ 966

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 IPO 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 IPO, 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 - The Company has never declared nor paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and therefore, used an expected dividend yield of zero.

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, 2020 and 2021:

	Year Ended December 31, 2020	Year Ended December 31, 2021
Expected volatility	114.00%	101.00 – 105.00%
Risk-free interest rate	0.44 - 0.51%	0.61 – 1.34%
Dividend yield	-%	-%
Expected term	6.25 years	5.13 – 6.25 years

11. 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, 2020 and 2021 is as follows:

	Year Ended December 31, 2020	Year Ended December 31, 2021
Income taxes (benefit) at statutory rates	21.00%	21.00%
State income tax (benefit), net of federal benefit	6.20	-
Change in valuation allowance	(26.30)	(16.27)
Interest on convertible notes	(2.20)	(2.22)
Others	1.30	(2.51)
Effective income tax rate	-%	-%

For the years ended December 31, 2020 and 2021, the Company did not record a deferred income tax expense or benefit. Income tax expense has been nominal for the years ended December 31, 2020 and 2021.

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, 2020 and 2021 are shown below (in thousands):

	December 31, 2020	December 31, 2021
Deferred tax assets:		
Stock-based compensation	$ 71	$ 226
Net operating losses carryforwards	1,072	2,257
Depreciation and Amortization	63	468
Accrued expenses	251	135
Gross deferred tax assets	1,457	3,086
Less: Valuation allowance	(1,457)	(3,086)
Deferred tax assets, net of valuation allowance	$ -	$ -

The valuation allowance increased by $1.6 million during the year ended December 31, 2021. We have concluded, based upon ASC 740, that it is more likely than not we will not realize any benefit from the deferred tax assets related to certain Federal and state's net operating loss and credit carryforward. Accordingly, the Company has established a full valuation allowance against its Federal and state deferred tax assets.

As of December 31, 2021, the Company had available Federal and California net operating loss carryforwards of approximately $9.5 million and $3.9 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, 2021, the Company had research and development credit carryforwards of approximately $900 and $100,000 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, 2021 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 is not expected to 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 following table summarizes the changes to the Company's gross unrecognized tax benefits for the years ended December 31, 2020 and 2021 (in thousands):

	Year Ended December 31, 2020	Year Ended December 31, 2021
Beginning balance	$ 12	$ 29
Additions related to current year positions	17	72
Ending balance	$ 29	$ 101

As of December 31, 2020 and 2021, the total unrecognized tax benefit was approximately $29,000 and $101,000, 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, 2021, 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 2017 and forward remain open to examination due to the carryover of NOL carryforwards. There are no ongoing examinations by taxing authorities at this time.

12. 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, 2020	Year Ended December 31, 2021
Numerator:		
Net loss	$ (2,264)	$ (10,017)
Denominator:		
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	8,499,687	11,675,750
Net loss per share attributable to common stockholders, basic and diluted	$ (0.27)	$ (0.86)

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, 2020	Year Ended December 31, 2021
Options to purchase common stock	786,047	1,211,068
Warrants to purchase common stock	-	4,784,193
Total	786,047	5,995,261

13. Subsequent Events

On January 6, 2022, the Company entered into a Master Services Agreement with Quotient Sciences Limited, a UK based company that provides drug development and analysis services, for the purpose of performing clinical research in support of UNI-494.

On February 9, 2022, the Company entered into a Master Services Agreement with CBCC Global Research Inc., a California based company that provides clinical trial and related service, for the purpose of performing clinical research in support of Renazorb.

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, 2021, 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, 2021, 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 resulted in insufficient time spent on 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;
- Begin discussions with third party experts to assist management in completing a comprehensive risk assessment to identify, design and implement control activities; and
- Begin reviewing and enhancing business policies, procedures and related internal controls to standardize business processes.

We expect to complete the remediation by the end of 2022. 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, 2021, 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, 2021, 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 resulted in insufficient time spent on 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;
- Begin discussions with third party experts to assist management in completing a comprehensive risk assessment to identify, design and implement control activities; and
- Begin reviewing and enhancing business policies, procedures and related internal controls to standardize business processes.

We expect to complete the remediation by the end of 2022. 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 following table sets forth the name, age and positions of our executive officers and directors as of March 31, 2022:

Name	Age	Position
Shalabh Gupta, M.D.	48	Chief Executive Officer, President and Chairman of the Board of Directors
Pramod Gupta, Ph.D.	62	Executive Vice President, Pharmaceutical and Business Operations
John Townsend	60	Chief Financial Officer
John Ryan, M.D., Ph.D.	78	Director
Sandeep Laumas, M.D.	53	Director
Brigitte Schiller, M.D. (1)	61	Director

The business background and certain other information about our directors and executive officers is set forth below.

Shalabh Gupta, M.D. Shalabh Gupta, our founder, has served as our Chief Executive Officer, President and director since August 2016. Since June 2013, Dr. Gupta has also served as the founder and Chief Executive Officer of Globavir Biosciences, Inc., a company focused on commercializing novel therapeutics and powerful diagnostics for treating global infectious disease. Dr. Gupta has also served in various other capacities including founder and Chief Executive Officer of Biocycive Inc.; Strategy, Genentech Commercial at Genentech, Inc.; Equity Research, Pharmaceuticals at UBS Investment Bank; Attending Physician at NYU Medical Center; clinical faculty member at NYU School of Medicine; and Equity Research, Biotechnology at Rodman & Renshaw, LLC. In addition, he has served on the board of directors of Beall Center for Innovation and Entrepreneurship since 2018. Dr. Gupta has also served as an advisor to SPARK, Stanford University School of Medicine since 2012, a charter member of TiE, a not-for-profit network of entrepreneurs fostering entrepreneurship, mentoring and education, since 2013. Dr. Gupta previously served on the board of directors of Phenomenome Discoveries Inc. and was a Fellow at the Startup Leadership Program, a medical advisor Synageva BioPharma Corporation (formerly known as AviGenics) and an advisor to NYU Langone Medical Center (Office of Technology Transfer). Dr. Gupta received his MPA in health care finance and management from NYU Robert F. Wagner Graduate School of Public Service, and his medical degree from Jawaharlal Institute of Postgraduate Medical Education & Research, India. Furthermore, Dr. Gupta completed his internship in Internal Medicine, and medical residency in physical medicine and rehabilitation and a research fellowship in cardiopulmonary rehabilitation from New York University ("NYU") School of Medicine and New York University. He practiced medicine from 2000 to 2008 at NYU's various hospitals first during his medical training (2000-2004) and then as an attending physician (2004-2008). Dr. Gupta also served as a faculty member at NYU School of Medicine. In the past, Dr. Gupta was a board-certified physician, and he currently holds a license from the California State Medical Board. While working as a stock analyst on Wall Street, Dr. Gupta held Series 7, 63, 86 and 87 licenses. We believe Dr. Gupta is qualified to serve as a member of our board of directors because of his background as a physician and as a biotechnology executive and his extensive experience in both in-licensing technologies from academic institutions and biotechnology companies as well as out-licensing technologies to larger organizations in addition to his former experience on Wall Street.

Pramod Gupta, Ph.D. Dr. Gupta has served as our Executive Vice President, Pharmaceutical and Business Operations since September 2020. Dr. Gupta is a pharmaceutical executive with 30 years' experience at large as well as small companies. He has extensive experience in drug development, regulatory requirements and drug approvals globally. He has led development/approval/launch of over 40 products by leveraging external partnerships/technologies/business solutions. Previously Dr. Gupta served as the Senior Vice President at Spectrum Pharmaceuticals from January 2011 to April 2018, Vice President at Bausch & Lomb from May 2005 to August 2009, and at positions of increasing responsibilities at Baxter, TAP Pharmaceuticals and Abbott Laboratories. He has published more than 50 scientific papers and 2 scientific books, and holds 14 patents. He completed his PhD from the University of Otago New Zealand.

John Townsend. Mr. Townsend has served as our Chief Financial Officer starting in March 2021, and he has previously served as Vice President Finance and Chief Accounting Officer in a consulting role since September 2020. He has over 25 years of public and private company experience in industries including biotechnology, medical devices, and high-tech electronics manufacturing. Before joining the Company, Mr. Townsend worked at Guardion Health Sciences, a medical foods company from 2016 to 2020. From 2005 until 2015, he worked at Cytori Therapeutics, Inc., a stem cell therapy company. From 1996 to 2005, he worked at several high-tech companies, and he started his career at Deloitte (formerly Deloitte and Touche) after graduating from San Diego State University in 1993. Mr. Townsend is a Certified Public Accountant in the state of California.

John Ryan, M.D., Ph.D. John Ryan has served as our director since 2018. Since 2011, Dr. Ryan has served as Executive Vice President, Chief Medical Officer of Kadmon Holdings, Inc., a biopharmaceutical company engaged in the discovery, development and commercialization of small molecules and biologics. From 2009 until 2011, Dr. Ryan served as Senior Vice President and Chief Medical Officer of Cerulean Pharma, Inc., a publicly traded pharmaceutical company, and from 2006 until 2009, he served as Chief Medical Officer at Aveo Pharmaceuticals, Inc. (Nasdaq: AVEO), a biopharmaceutical company seeking to advance targeted medicines for oncology and other unmet medical needs. From 1995 until 2006, Dr. Ryan served as Senior Vice President of Translational Research at Wyeth (formerly Genetics Institute), where he served as head of the Department of Experimental Medicine. Dr. Ryan also served as an Executive Director of Clinical Research at Merck Research Laboratories from 1989 to 1995 and he previously served on the scientific advisory boards of ArQule, Inc. and Expression Analysis, Inc. Dr. Ryan has also been a director of Globavir Biosciences, Inc. since 2014. Dr. Ryan received his B.S. and his Ph.D. from Yale University. Dr. Ryan received his M.D. from the University of California, San Diego. We believe Dr. Ryan is qualified to serve as a member of our board of directors because of his clinical background and extensive experience in running clinical development programs and getting drugs through the FDA approval process.

Sandeep Laumas, M.D. Sandeep Laumas has served as our director since 2018. Since 2014, Dr. Laumas has served on the board of directors of private and publicly traded biotechnology companies. In 2008, Dr. Laumas founded Bearing Circle Capital, an investment vehicle and has served as its Managing Director since such time. Dr. Laumas began his career at Goldman Sachs & Co. in 1996 as an equity analyst in the healthcare investment banking division working on mergers & acquisitions and corporate finance transactions before transitioning to the healthcare equity research division. After leaving Goldman Sachs in 2000, Dr. Laumas moved to the buy side as an analyst at Balyasny Asset Management from 2001 to 2003. Dr. Laumas was a Managing Director of North Sound Capital from 2003 to 2007, where he was responsible for the global healthcare investment portfolio. Dr. Laumas has served as a member of the board of directors of private and public healthcare companies including, Parkway Holdings Ltd. (2010), SRL Ltd. (2011-2012), 9 Meters Biopharma, Inc. (2018-present) and BioXcel Therapeutics, Inc. (2017-present). Dr. Laumas has also been a director of Globavir Biosciences, Inc. since 2015. Dr. Laumas received his A.B. in Chemistry from Cornell University in 1990, M.D. from Albany Medical College in 1995 with a research year at the Dana-Farber Cancer Institute and completed his medical internship in 1996 from the Yale University School of Medicine. We believe Dr. Laumas is qualified to serve as a member of our board of directors because his vast industry perspective in both public and private investments and financial transactions in the healthcare arena.

Brigitte Schiller, M.D., FACP, FASN. Dr. Schiller has served as our director since 2020. Dr. Schiller has been Chief Medical Officer at Satellite Healthcare since 2010. In this role, Dr. Schiller is responsible for Quality, Physician Leadership and Research & Development. She oversees the development and implementation of the quality strategy, its execution and organizational infrastructure. Dr. Schiller serves as Chief of Staff, and as such provides oversight on more than 80 medical directors and over 400 referring physicians. As CMO Dr. Schiller is responsible for the delivery of care to more than 8,000 dialysis patients in 80 US centers. She directs Satellite's clinical research efforts, which by deliberate policy are applied pragmatic real-world studies directed towards improvement in patient experience and outcomes. Under her leadership, Satellite Healthcare has achieved the highest quality ratings in the CMS 5 Star Ratings for several years. Dr. Schiller has participated as investigator in multiple FDA trials, including pivotal drug and device trials in ESRD care over the past 15 years. She is a published author in many areas of ESRD care, including home dialysis. She is known as an inspirational leader who is determined to transform the care of patients with chronic kidney disease through quality improvement efforts, innovative drugs and devices as well as alternative care models unchanged since 1973. She has been a consultant to various early-stage and established healthcare companies. Dr. Schiller serves as an Adjunct Lecturer in the Division of Nephrology at Stanford University. She is a frequent invited speaker at national and international meetings. She has received teaching and research awards including the 2017 Woman of Influence award for executives. She serves on the Expert Panel for the USRDS database. Dr. Schiller graduated MD summa cum laude from the University of Freiburg, Germany and, in addition to postgraduate training at the University of Munich, completed residency and research fellowships at Rush-Presbyterian-St. Luke's Medical Center, Chicago, Northwestern University and the University of Chicago.

Chief Development Advisor

Keith Ward, Ph.D. Dr. Ward is a life sciences executive with over 25 years of experience in the biotech and pharmaceutical industry. In addition to his role at Unicycive, Dr. Ward serves in leadership and Board positions for several emerging biotech and pharma companies. Prior to joining Unicycive in an advisory capacity, Dr. Ward served as Executive Vice President and Chief Development Officer for Reata Pharmaceuticals, from July 2011 through March 2019 and led research and development, clinical operations, regulatory affairs, manufacturing, and project management. Before that, Dr. Ward developed ophthalmic pharmaceuticals and medical devices as Global Vice President of Pharmaceutical R&D for Bausch & Lomb from May, 2005 to June, 2011. Dr. Ward has also held positions of increasing responsibility within GlaxoSmithKline and SmithKline Beecham Pharmaceuticals. Dr. Ward earned a B.S. in Toxicology with a minor in Chemistry from Northeast Louisiana University and a Ph.D. in Toxicology from The University of North Carolina at Chapel Hill.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Arrangements between Officers and Directors

Except as set forth in this Annual Report on Form 10-K, to our knowledge, there is no arrangement or understanding between any of our officers or directors and any other person pursuant to which such officer or director was selected to serve as an officer or director of the Company.

Involvement in Certain Legal Proceedings

We are not aware of any of our directors or officers being involved in any legal proceedings in the past ten years relating to any matters in bankruptcy, insolvency, criminal proceedings (other than traffic and other minor offenses), or being subject to any of the items set forth under Item 401(f) of Regulation S-K.

Committees of Our Board of Directors

Our board of directors directs the management of our business and affairs, as provided by Delaware law, and conducts its business through meetings of the board of directors and its standing committees. We have a standing audit committee, compensation committee and corporate governance and nominating committee. In addition, from time to time, special committees may be established under the direction of the board of directors when necessary to address specific issues.

Audit Committee

Our audit committee is responsible for, among other things:

- approving and retaining the independent auditors to conduct the annual audit of our financial statements;
- reviewing the proposed scope and results of the audit;
- reviewing and pre-approving audit and non-audit fees and services;
- reviewing accounting and financial controls with the independent auditors and our financial and accounting staff;
- reviewing and approving transactions between us and our directors, officers and affiliates;
- establishing procedures for complaints received by us regarding accounting matters;
- overseeing internal audit functions, if any; and
- preparing the report of the audit committee that the rules of the SEC require to be included in our annual meeting proxy statement.

Our audit committee consists of Dr. Laumas, Dr. Ryan, and Dr. Schiller, with Dr. Laumas serving as chair. Our board of directors has affirmatively determined that each meets the definition of "independent director" under the Nasdaq rules, and that they meet the independence standards under Rule 10A-3. Each member of our audit committee meets the financial literacy requirements of the Nasdaq rules. In addition, our board of directors has determined that Dr. Laumas qualifies as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K. Our board of directors has adopted a written charter for the audit committee, which is available on our principal corporate website at *http://www.unicycive.com*.

Compensation Committee

Our compensation committee is responsible for, among other things:

- reviewing and recommending the compensation arrangements for management, including the compensation for our chief executive officer;
- establishing and reviewing general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve our financial goals;
- administering our stock incentive plans; and
- preparing the report of the compensation committee that the rules of the SEC require to be included in our annual meeting proxy statement.

Our compensation committee consists of Dr. John Ryan and Dr. Sandeep Laumas, with John Ryan serving as chair. Our board has determined that the committee members are independent directors under Nasdaq rules. Our board of directors has adopted a written charter for the compensation committee, which is available on our principal corporate website at *http://www.unicycive.com*.

Nominating and Governance Committee

Our nominating and governance committee is responsible for, among other things:

- identifying and nominating members of the board of directors;
- developing and recommending to the board of directors a set of corporate governance principles applicable to our Company; and
- overseeing the evaluation of our board of directors.

Our nominating and corporate governance committee consists of Dr. Schiller and Dr. Ryan, with Dr. Schiller serving as chair. Our board has determined that the committee members are independent directors under Nasdaq rules. Our board of directors has adopted a written charter for the nominating and governance committee, which is available on our principal corporate website at *http://www.unicycive.com*.

Scientific Advisory Board

Ravi Mehta, M.D.

Dr. Mehta is a Professor Emeritus of Medicine in the Department of Medicine at University of California San Diego where he directs the UCSD Masters in Clinical Research Program. He is an internationally recognized expert in the field of acute kidney injury (AKI) and continuous renal replacement therapies (CRRT). He holds a patent for "Continuous Hemodialysis Using Citrate". He chairs the annual International AKI and CRRT Conference in San Diego that is now in its 25th year. He chaired the International Society of Nephrology (ISN) Committee on AKI, is a founding member of the Acute Dialysis Quality Initiative (ADQI) and the Acute Kidney Injury network (AKIN), a member of the KDIGO Guidelines in AKI committee and served as the director of the ISN 0 by 25 initiative to eliminate preventable deaths from AKI by 2025. He has coordinated and led several multinational efforts for determining best approaches for managing AKI and CRRT. These have included the IHD vs CRRT trial, The PICARD network, the DIRECT study evaluating the genetic determinants of drug induced nephrotoxicity and the ISN 0by25 initiative. He has more than 200 original research publications, 100 reviews and book chapters. He has served on the NIH NIDDK study section and special emphasis panels and on editorial boards of the Journal of

American Society of Nephrology, Kidney International and CJASN. He has been on the program committee of the ISN and contributed to the annual meetings of the American Society of Nephrology, National kidney Foundation and ISICEM. He has coordinated the development of consensus recommendations including the RIFLE and AKIN diagnostic and staging criteria for AKI. He has been recognized as one of the Best Doctors in San Diego and the US for several years. In 2008 he was recognized by the American Nephrologists of Indian Origin and in March 2009 he was elected as a Fellow of the Royal College of Physicians in the UK. He received the International Society of Nephrology (ISN) Bywaters Award for lifetime achievement in AKI in April 2011. He received the M.B.B.S. degree (1976) from the Government Medical School in Amritsar, India, and the M.D. (1979) and D.M. (1981) degrees from the Post Graduate Institute of Medical Education and Research in Chandigarh, India. He subsequently completed a nephrology fellowship at the University of Rochester in Rochester New York and obtained his boards in Internal Medicine (1986) and Nephrology (1988). He has been on the faculty at San Diego since 1988.

Myles Wolf, MD, MMSc. Dr. Wolf is Charles Johnson, MD, Professor of Medicine and Chief of the Division of Nephrology at the Duke University School of Medicine. Dr. Wolf received his MD from the State University of New York–Downstate, completed Internal Medicine and Nephrology training at the Massachusetts General Hospital, and obtained a Master of Medical Sciences degree in Clinical and Physiological Investigation from Harvard Medical School. After serving on the Harvard faculty for 5 years, Dr. Wolf moved to the University of Miami Miller School of Medicine, where he eventually served as Chief of the Division of Nephrology and Hypertension, Director of the Clinical Research Center, and Assistant Dean for Translational and Clinical Research. Subsequently, he spent 3 years at Northwestern University Feinberg School of Medicine as founding Director of the Center for Translational Metabolism and Health and as Director of the Department of Medicine's Physician-Scientist Training Program. Dr. Wolf moved to Duke in 2013. As Chief of Duke Nephrology, Dr. Wolf mentors, manages and leads >40 clinical and research faculty, >12 nephrology fellows, 5 advanced practice practitioners, an administrative and research staff of >30 professionals, and many rotating students and postdoctoral PhD trainees. Managing an annual operating budget of more than $15M, Dr. Wolf is responsible for developing the vision and executing the operational strategy of Duke Nephrology across its clinical, research and educational missions.

The focus of Dr. Wolf's clinical trials, patient-oriented, epidemiological, and laboratory research is disordered mineral metabolism across the spectrum of kidney disease from early stages to end-stage renal disease and following kidney transplantation. His primary contributions have been to characterize the central role of fibroblast growth factor 23 in phosphate and calcium homeostasis in health and in disease, and the deleterious effects of excess fibroblast growth factor 23 that increase risks of cardiovascular disease and death. Since 2002, Dr. Wolf's research has been supported by the American Heart Association, National Kidney Foundation, American Society of Nephrology, and National Institutes of Health. As Principal Investigator, he has been the recipient of more than $25 million of extramural grant support throughout his career. Having served on Steering Committees and as Principal Investigator of multiple industry- and federally-sponsored clinical trials, Dr. Wolf is currently PI of "HiLo," which is a randomized multicenter pragmatic clinical outcomes trial of phosphate management in patients with end-stage renal disease. Dr. Wolf has published his research in *N Engl J Med, JAMA, J Clin Invest, Circulation, Cell Metabol, J Am Soc Nephrol,* and *Kidney Int,* among others.

Dr. Wolf has been primary research mentor for students, residents, fellows, and faculty, many of whom are now independent investigators and national leaders in academic nephrology. He has served on editorial boards for *J Am Soc Nephrol, Clin J Am Soc Nephrol, Semin Nephrol*, and *Nat Rev Nephrol*, as an ad hoc reviewer for several other journals, and as Editor of the Mineral Metabolism section of *Curr Opin Nephrol Hypertens.* Dr. Wolf has delivered numerous invited lectures on his research domestically and internationally, and has received several teaching, mentoring and research awards. In recognition of his scientific contributions, Dr. Wolf was elected to the American Society of Clinical Investigation in 2010 and the Association of American Physicians in 2017. He received the 2014 Young Investigator Award from the American Society of Nephrology, and was elected to the Council of the International Society of Nephrology in 2017 and as Chair of its North American and Caribbean Regional Board in 2019. In 2020, Dr. Wolf was appointed to the Board of Directors of Akebia Therapeutics, Inc.

Pablo Pergola, MD, PhD Dr. Pergola, MD, Ph.D. is the research director of the Clinical Advancement Center, PLLC, and a member of Renal Associates PA, a large nephrology practice serving patients in San Antonio, Texas and surroundings. He joined the practice in 2005 after working as an Assistant Professor of Medicine, UT Health San Antonio and the Audie L. Murphy VA Hospital in San Antonio for 6 years. Dr. Pergola leads a talented and dedicated group of professionals with the common goal of serving patients with kidney disease through advancements in science and medicine.

Dr. Pergola maintains a busy practice while dedicating significant effort to conducting clinical studies. He sees patients in the outpatient clinics, dialysis units and hospitals. Dr. Pergola is fluent in English and Spanish. He is board-certified in Nephrology. He remains academically very active; he is an author in numerous publications and abstract presentations at national and international meetings. He is also a consultant for several pharmaceutical companies that value his experience in protocol development and mechanisms of kidney disease.

Dr. Pergola studied Medicine in Buenos Aires, Argentina, at the School of Medicine, Universidad del Salvador. He then received his PhD in Pharmacology, graduating with honors from the University of Kansas Medical Center, Kansas City. After obtaining additional post-doctoral training in basic and clinical research in the Department of Physiology, UT Health San Antonio, he completed his Internal Medicine internship and residency and Nephrology fellowship at UT Health San Antonio.

Glenn Chertow, MD, MPH Dr. Chertow, MD, MPH is the Norman S. Coplon Satellite Healthcare Professor of Medicine and (by courtesy) of Epidemiology and Population Health, and Chief, Division of Nephrology at Stanford University School of Medicine. Dr. Chertow completed his undergraduate education at University of Pennsylvania (1985) and his MD (1989) and MPH (1995) degrees at Harvard. He completed residency in internal medicine and fellowship in nephrology at Brigham and Women's Hospital before joining the Harvard faculty, where he remained until 1998. He then joined the faculty at University of California San Francisco, where he served as Director of Clinical Services in the Division of Nephrology and was promoted through the academic ranks to full Professor in the Departments of Medicine and Epidemiology and Biostatistics until joining the Stanford faculty as Professor and Division Chief in 2007. In addition to an active clinical practice, administrative responsibilities, teaching and mentoring, Dr. Chertow has developed and maintained a robust clinical research program. He has served or is currently serving in leadership roles for multiple NIDDK-, NHLBI-, and VA-sponsored clinical trials, including HEMO, DAC, ATN, FHN, SPRINT, PRESERVE, ISCHEMIA CKD, CURE-GN and TiME, and for several industry-sponsored clinical trials including TREAT, EVOLVE, BEACON, SYMPLICITY, REPRISE, CREDENCE, and DAPA-CKD. He has served in an advisory capacity to the Medicare Payment Advisory Committee and the National Quality Forum on issues related to the ESRD program, on NIH study sections and in multiple roles with the American Society of Nephrology (ASN), including the Public Policy Board, Quality Metrics Taskforce, and as Associate Editor of the society's leading journal. He is Co-Editor of Brenner and Rector's The Kidney. Dr. Chertow was honored by the American Kidney Fund in 2007 with the National Torchbearer Award and in 2011 with the Nephrologist of the Year Award, in recognition of his contributions to the care of persons with kidney disease. Dr. Chertow was elected to the American Society of Clinical Investigation in 2004, and in 2015, received the Belding H. Scribner Award from ASN and was elected to the Association of American Physicians and the National Academy of Medicine (formerly Institute of Medicine). In 2018, Dr. Chertow received the David M. Hume Memorial Award, the highest honor given by the National Kidney Foundation to a distinguished scientist-clinician in the field of kidney and urologic diseases.

Suneel Gupta, Ph.D. Dr. Gupta is currently the Chief Development Officer at Protagonist. Previously, he was Chief Scientific Officer at Impax Pharmaceuticals, having joined them in 2008 and before that Dr. Gupta previously was with ALZA Corporation, a wholly owned subsidiary of Johnson & Johnson, for nearly 20 years. There, he was responsible for the strategic vision and execution of clinical research and development as Senior Vice President and distinguished research fellow. Dr Gupta's research interest focuses on the influence of rate and route of drug delivery to discover new indications, as well as maximize clinical utility and/or effectiveness. With extensive experience in the development of drug delivery-based products across many therapeutic areas, Dr. Gupta has made significant contributions to the development of several

therapeutics including Duragesic®, Durotap®, Nicoderm®, Testoderm®, Effidac®, Covera-HS®, Ditropan-XL®, Concerta®, Ionsys®, Jurnista®, Invega® and Priligy®. Before ALZA, he worked at Ciba Geigy (India) where he was responsible for scale-up and manufacturing of several products. Dr. Gupta received his PhD from the University of Manchester and was a Postdoctoral Fellow at UCSF. He is a coauthor on more than 200 research publications and co-inventor on more than 40 patents.

Dominic Marasco, R.Ph. Mr. Marasco is the Chief Commercial Officer of BioAgilytix Labs, based in Durham, NC. He has more than 20 years of executive experience in C-suite strategic planning, commercial operations, global business development, clinical PhIII trial design strategy, alliance management, financial resourcing and P&L oversight within the Pharmaceutical, Biotech and Medical Device industries.

Prior to joining BioAgilytix, he served as Executive Vice President, Global Business Development, Commercial at Syneos Health, where he led the overall strategic direction of the global business development team for the commercial division both in the U.S. and internationally. He was also previously Head of U.S. Sales for the Neuroscience Business Unit at Amgen, Inc. and prior to that Global Commercial Head, Amgen Biosimilars. Mr. Marasco has also held executive-level commercial and business development positions at Sandoz Biopharmaceuticals (a Novartis company) and IQVIA (formerly Quintiles).

Mr. Marasco is a University of Southern California Adjunct Associate Professor of Pharmaceuticals and Health Economics for the School of Pharmacy and a member of the Health Policy and Management Executive Council at the Harvard T.H. Chan School of Public Health. He received his Bachelor of Science in Pharmacy from the Philadelphia College of Pharmacy and is a registered pharmacist with a current active licensure.

Our arrangements with these individuals do not entitle us to any of their existing or future intellectual property derived from their independent research or research with other third parties.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than 10% of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. To our knowledge, based solely upon a review of Forms 3, 4, and 5 filed with the SEC during the fiscal year ended December 31, 2021, we believe that, our directors, executive officers, and greater than 10% beneficial owners have complied with all applicable filing requirements during the fiscal year ended December 31, 2021.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is filed as an exhibit to this Annual Report on Form 10-K and is posted on our website, *www. unicycive.com.* We intend to post on our website all disclosures that are required by law or Nasdaq rules concerning any amendments to, or waivers from, any provision of the code.

Changes in Nominating Procedures

None.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the total compensation paid or accrued during the years ended December 31, 2020 and 2021 to our named executive officers:

Name and Principal Position	Year	Salary[1] ($)	Bonus[1] ($)	Option Awards [2] ($)	All Other Compensation [3] ($)	Total ($)
Shalabh Gupta, M.D.,	2021	669,775	124,187	330,729	-	1,124,691
Chief Executive Officer	2020	495,000	148,500	-	-	643,500
Pramod Gupta, Ph.D.,	2021	187,500	-	231,555	68,750	487,805
Executive VP Pharmaceutical and Business Operations	2020	-	-	212,250	60,000	272,250
John Townsend, CPA,	2021	91,667	-	185,253	106,197	383,117
Chief Financial Officer	2020	-	-	-	39,750	39,750

(1) Represents salary and bonus earned, but not all paid.

(2) Represents the aggregate grant date fair values of stock option awards in accordance with FASB ASC No. 718-10. These values have been determined under the principles used to calculate the grant date fair market value of equity awards for purposes of the Company's financial statements. The fair value of the common stock underlying the Company's stock options prior to the IPO 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 IPO, the fair value underlying the Company's common stock is determined based on the public market closing price on each date of grant. Other assumptions used in our valuation of grants include expected term, volatility, and a risk-free interest rate.

(3) Represents consulting fees earned prior to commencing formal employment with the Company.

Outstanding Equity Awards at December 31, 2021

The following table provides information regarding awards held by each of our named executive officers that were outstanding as of December 31, 2021.

Name and Principal Position	Number of Securities Underlying Unexercised Options (#) (Exercisable)	Number of Securities Underlying Unexercised Options (#) (Unexercisable)	Option Exercise Price ($)	Option Expiration Date
Shalabh Gupta, M.D., *Chief Executive Officer*	-	170,543	0.13 – 5.00	8/2023 – 7/2031
Pramod Gupta, Ph.D., *Executive VP Pharmaceutical and Business Operations*	63,710	128,152	3.27 – 7.01	10/2029 – 7/2031
John Townsend, CPA, *Chief Financial Officer*	-	41,861	5.00 – 7.01	3/2031 – 7/2031

Non-Employee Director Compensation

The following table sets forth the total compensation paid or accrued during the years ended December 31, 2020 and 2021 to our non-employee directors:

Name	Year	Option Awards [2] ($)	Fees Earned or Paid in Cash ($)	Total ($)
Sandeep Laumas, M.D. [1]	2021	-	27,500	27,500
	2020	-	-	-
John Ryan, M.D., Ph.D. [2]	2021	-	24,750	24,750
	2020	-	-	-
Brigitte Schiller, M.D. [3]	2021	150,000	25,438	175,438
	2020	-	-	-

(1) Dr. Laumas was paid $27,500 as compensation for services as a member of the board of directors, chairman of the audit committee, and member of the compensation committee.

(2) Dr. Ryan was paid $24,750 as compensation for services as a member of the board of directors, chairman of the compensation committee, and member of the nomination and corporate governance committee.

(3) Dr. Schiller was paid $25,438 as compensation for services as a member of the board of directors, chairman of the nomination and corporate governance committee, and member of the audit committee. In connection with Dr. Schiller's appointment to the board of directors in 2021, she received an option grant worth $50,000 on the date of grant and a restricted stock unit award worth $100,000 on the date of grant.

Employment Agreements

Shalabh Gupta Employment Agreement

On May 18, 2021, we entered into an employment agreement with Dr. Gupta, pursuant to which Dr. Gupta serves as our Founder and Chief Executive Officer. Dr. Gupta's employment agreement provides for an annual base salary of $550,000 and provides that Dr. Gupta will be eligible for an annual discretionary bonus, with a target equal to 100% of his base salary, based on the achievement of certain performance objectives established by our Board of Directors. In accordance with the terms of Dr. Gupta's employment agreement, he received a one-time equity grant of 116,279 stock options, which shall vest over a period of three years from the date of grant. In addition, Dr. Gupta's employment agreement contains standard non-competition and non-solicitation provisions. Dr. Gupta is also eligible to receive additional equity-based compensation awards as the Company may grant from time to time. Dr. Gupta's employment agreement further provides for standard expense reimbursement, vacation time and other standard executive benefits.

Pursuant to Dr. Gupta's employment agreement, in the event his employment is terminated without cause, due to a non-renewal by the Company, or if he resigns for "good reason" (in each case, other than within twelve (12) months following a change in control), Dr. Gupta is entitled to (i) a cash payment equal to one and one-half (1.5) times the sum of his (x) annual base salary and (y) target bonus in effect on his last day of employment; (ii) continuation of health benefits for a period of 18 months; (iii) a lump sum payment equal to the amount of any annual bonus earned with respect to a prior fiscal year, but unpaid as of the date of termination; (iv) a lump sum payment equal to the amount of annual bonus that was accrued through the date of termination for the year in which employment ends; and (v) subject to Dr. Gupta's compliance with his restrictive covenants, the outstanding and unvested portion of any time-vesting equity award that would have vested during the one (1) year period following Dr. Gupta's termination had he remained an employee shall automatically vest upon his termination date.

In the event that Dr. Gupta's employment is terminated due to his death or disability, he will be entitled to receive (i) a lump sum payment equal to the amount of any annual bonus earned with respect to a prior fiscal year, but unpaid as of the date of termination; (ii) a lump sum payment equal to the amount of annual bonus that was accrued for the year in which employment ends; and (iii) the acceleration and vesting in full of any then outstanding and unvested portion of any time-vesting equity award granted to him by the Company.

In the event that Dr. Gupta's employment is terminated due to his non-renewal or resignation without "good reason," he will be entitled to receive a lump sum payment equal to the amount of any annual bonus earned with respect to a prior fiscal year, but unpaid as of the date of termination.

In the event that Dr. Gupta's employment is terminated by the Company without cause, due to non-renewal by the Company, or if he resigns for "good reason," in each case within twelve (12) months following a change in control, Dr. Gupta is entitled to (i) a cash payment equal to two (2) times the sum of his (x) annual base salary and (y) target bonus in effect on his last day of employment; (ii) continuation of health benefits for a period of 24 months; (iii) a lump sum payment equal to the amount of any annual bonus earned with respect to a prior fiscal year, but unpaid as of the date of termination; (iv) a lump sum payment equal to the amount of annual bonus that was accrued for the year in which employment ends prior to the date of termination; and (v) the acceleration and vesting in full of any then outstanding and unvested portion of any time-vesting equity award granted to him by the Company.

Pramod Gupta Employment Agreement

On March 22, 2021 (as amended April 28, 2021), we entered into an employment agreement with Mr. Gupta, pursuant to which Mr. Gupta serves as our Executive Vice

President, Pharmaceutical and Business Operations. Mr. Gupta's employment agreement provides for an annual base salary of $450,000 and provides that Mr. Gupta will be eligible for an annual discretionary bonus, with a target amount equal to 50% of his base salary, based on the achievement of certain performance objectives established by our Board of Directors. In accordance with the terms of Mr. Gupta's employment agreement, he received a one-time equity grant of 34,884 stock options, which shall vest over a period of three years from the date of grant. In addition, Mr. Gupta's employment agreement contains standard non-competition and non-solicitation provisions. Mr. Gupta is also eligible to receive additional equity-based compensation awards as the Company may grant from time to time. Mr. Gupta's employment agreement further provides for standard expense reimbursement, vacation time and other standard executive benefits.

Pursuant to Mr. Gupta's employment agreement, in the event his employment is terminated without cause, due to non-renewal by the Company, or if he resigns for "good reason," (in each case, other than within twelve (12) months following a change in control), Mr. Gupta is entitled to (i) a cash payment equal to the sum of his (x) annual base salary and (y) target bonus in effect on his last day of employment; (ii) continuation of health benefits for a period of 12 months; (iii) a lump sum payment equal to the amount of any annual bonus earned with respect to a prior fiscal year, but unpaid as of the date of termination; (iv) a lump sum payment equal to the amount of annual bonus that was accrued through the date of termination for the year in which employment ends; and (v) subject to Mr. Gupta's compliance with his restrictive covenants, the outstanding and unvested portion of any time-vesting equity award that would vest on the next vesting date shall automatically vest upon his termination date, multiplied by a fraction, where the numerator is the number of days Mr. Gupta was employed since the last vesting date (or the date of grant, if such termination occurs prior to the first vesting date applicable to any such award) and the denominator is the total number of days since the last vesting date (or the date of grant, if such termination occurs prior to the first vesting date applicable to any such award) until the next vesting date.

In the event that Mr. Gupta's employment is terminated due to his death or disability, he will be entitled to receive (i) a lump sum payment equal to the amount of any annual bonus earned with respect to a prior fiscal year, but unpaid as of the date of termination; (ii) a lump sum payment equal to the amount of annual bonus that was accrued for the year in which employment ends; and (iii) the acceleration and vesting in full of any then outstanding and unvested portion of any time-vesting equity award granted to him by the Company.

In the event that Mr. Gupta's employment is terminated due to his non-renewal or resignation without "good reason," he will be entitled to receive a lump sum payment equal to the amount of any annual bonus earned with respect to a prior fiscal year, but unpaid as of the date of termination.

In the event that Mr. Gupta's employment is terminated by the Company without cause, due to non-renewal by the Company, or if he resigns for "good reason," in each case within twelve (12) months following a change in control, Mr. Gupta is entitled to (i) a cash payment equal to the sum of his (x) annual base salary and (y) target bonus in effect on his last day of employment; (ii) continuation of health benefits for a period of 12 months; (iii) a lump sum payment equal to the amount of any annual bonus earned with respect to a prior fiscal year, but unpaid as of the date of termination; (iv) a lump sum payment equal to the amount of annual bonus that was accrued for the year in which employment ends prior to the date of termination; and (v) the acceleration and vesting in full of any then outstanding and unvested portion of any time-vesting equity award granted to him by the Company.

John Townsend Employment Agreement

On July 2, 2021 we entered into an employment agreement with Mr. John Townsend, pursuant to which Mr. Townsend serves as our Chief Financial Officer. Mr. Townsend's employment agreement provides for an annual base salary of $220,000 and provides that Mr. Townsend will be eligible for an annual discretionary bonus, with a target amount equal to 30% of his base salary, based on the achievement of certain performance objectives established by our Board of Directors. In accordance with the terms of Mr. Townsend's employment agreement, he received a one-time equity grant of 18,605 stock options, which shall vest over a period of three years from the date of grant. In addition, Mr. Townsend's employment agreement contains standard non-competition and non-solicitation provisions. Mr. Townsend is also eligible to receive additional equity-based compensation awards as the Company may grant from time to time. Mr. Townsend's employment agreement further provides for standard expense reimbursement, vacation time and other standard executive benefits.

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

The following table sets forth certain information regarding the beneficial ownership of our common stock as of March 31, 2022 by:

- each of our named executive officers;
- each of our directors;
- all of our current directors and named executive officers as a group; and
- each stockholder known by us to own beneficially more than 5% of our common stock.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of March 31, 2022, pursuant to the exercise of options or warrants, vesting of common stock or conversion of convertible debt, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Percentage of ownership is based on 14,996,534 shares of common stock issued and outstanding as of March 31, 2022.

Unless noted otherwise, the address of all listed stockholders is c/o Unicycive Therapeutics, Inc., 4300 El Camino Real, Suite 210, Los Altos, CA 94022.

Except as indicated by the footnotes below, we believe, based on information furnished to us, that each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned	Percentage
Directors and Named Executive Officers:		
Shalabh Gupta, M.D.	5,841,726(1)	38.9%
John Townsend	6,298(2)	*%
John Ryan, M.D., Ph.D.	68,799(3)	*%

Sandeep Laumas, M.D.	116,474(4)	*%
Pramod Gupta, Ph.D.	81,152(5)	*%
Brigitte Schiller	-	*%
All current named executive officers and directors as a group (6 persons)	6,114,449	40.7%

* Represents beneficial ownership of less than 1%.

(1) Includes 20,349 shares of common stock issuable upon exercise of vested stock options and 6,783 shares of common stock issuable upon exercise of stock options that vest within 60 days of March 31, 2022. Excludes 27,132 shares of common stock issuable upon exercise of stock options that are subject to vesting.

(2) Includes 5,814 shares of common stock issuable upon exercise of vested stock options and 484 shares of common stock issuable upon exercise of stock options that vest within 60 days of March 31, 2022. Excludes 16,958 shares of common stock issuable upon exercise of stock options that are subject to vesting.

(3) Includes 10,417 shares of common stock issuable upon exercise of vested stock options and 242 shares of common stock issuable upon exercise of stock options that vest within 60 days of March 31, 2022. Excludes 969 shares of common stock issuable upon exercise of stock options that are subject to vesting.

(4) Includes 10,417 shares of common stock issuable upon exercise of vested stock options and 242 shares of common stock issuable upon exercise of stock options that vest within 60 days of March 31, 2022. Excludes 969 shares of common stock issuable upon exercise of stock options that are subject to vesting.

(5) Includes 77,881 shares of common stock issuable upon exercise of vested stock options and 3,271 shares of common stock issuable upon exercise of stock options that vest within 60 days of March 31, 2022. Excludes 110,710 shares of common stock issuable upon exercise of stock options that are subject to vesting.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table summarizes information about our equity compensation plans as of December 31, 2021.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
2018 Equity Incentive Plan	156,969	$ 0.01	-
2019 Stock Option Plan	425,949	$ 4.43	-
2021 Omnibus Equity Incentive Plan	628,150	$ 3.15	674,176
Total	1,211,068	$ 3.19	674,176

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

The following includes a summary of transactions during our fiscal year ended December 31, 2020 and 2021 to which we have been a party, including transactions in which the amount involved in the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described elsewhere in this Annual Report on Form 10-K. We are not otherwise a party to a related party transaction, and no transaction is currently proposed, in which the amount of the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years and in which a related person had or will have a direct or indirect material interest.

Service Agreement with Globavir Biosciences, Inc.

We entered into a Service Agreement on July 1, 2017, as amended on April 6, 2020 ("Service Agreement"), with Globavir Biosciences, Inc. ("Globavir"). Our Chief Executive Officer is also the Chief Executive Officer of Globavir. Pursuant to the Service Agreement, we receive administrative, consulting services, shared office space and other services in connection with our 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, we paid Globavir $50,000 per month through December 31, 2019 and $10,000 per month commencing on January 1, 2020. As of December 31, 2020, $9,000 was payable to Globavir for service fees. During the fourth quarter of 2021, we determined that future services under the Service Agreement were no longer required, and we wrote off the $28,000 remaining prepaid balance due from Globavir as of December 31, 2021. Service fee expenses were $120,000 and $148,000 for the years ended December 31, 2020 and 2021, respectively, and were recorded as general and administrative expenses in the statements of operations.

Related Person Transaction Policy

We have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds the lesser of $120,000 or 1% of our total assets at year-end. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Business Conduct and Ethics, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

Independence of the Board of Directors

Our board of directors undertook a review of the independence of our directors and considered whether any director has a relationship with us that could compromise that director's ability to exercise independent judgment in carrying out that director's responsibilities. Our board of directors has affirmatively determined that Dr. Laumas, Dr. Ryan, and Dr. Schiller are each an "independent director," as defined under Nasdaq rules.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the aggregate fees billed by Mayer Hoffman McCann ("MHM"). Substantially all MHM's personnel, who work under the control of MHM shareholders, are employees of wholly-owned subsidiaries of CBIZ, Inc., which provides personnel and various services to MHM in an alternative practice structure.

	2020	2021
Audit fees	$ 284,222	$ 327,411
Audit related fees	-	-
Tax fees	-	-
All other fees	-	-
Total	**$ 284,222**	**$ 327,411**

Audit Fees: Fees for audit services on an accrued basis.

Audit-Related Fees: Fees not included in audit fees that are billed by the auditor for assurance and related services that are reasonably related to the performance of the audit of the financial statements.

Tax Fees: Fees for professional services rendered for tax compliance, tax advice and tax planning.

All Other Fees: All other fees billed by the auditor for products and services not included in the foregoing categories.

Pre-Approval Policies and Procedures

In accordance with the Sarbanes-Oxley Act, our audit committee charter requires the audit committee to pre-approve all audit and permitted non-audit services provided by our independent registered public accounting firm, including the review and approval in advance of our independent registered public accounting firm's annual engagement letter and the proposed fees contained therein. The audit committee has the ability to delegate the authority to pre-approve non-audit services to one or more designated members of the audit committee. If such authority is delegated, such delegated members of the audit committee must report to the full audit committee at the next audit committee meeting all items pre-approved by such delegated members. In the fiscal years ended December 31, 2020 and 2021 all of the services performed by our independent registered public accounting firm were pre-approved by the audit committee.

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	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.5 to Amendment No. 2 to Form S-1 filed on June 21, 2021)
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 May 21, 2021)
4.4	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
10.1+	2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to Amendment No. 1 to Form S-1 filed on June 7, 2021)
10.2+	2019 Stock Option Plan (incorporated by reference to Exhibit 10.3 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 May 21, 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 10.3 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)
14.1	Code of Business Conduct and Ethics
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 Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document .
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 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on this 31st day of March, 2022.

UNICYCIVE THERAPEUTICS, INC.

/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 Annual Report on Form 10-K 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 (Principal Executive Officer), President and Chairman of the Board of Directors	March 31, 2022
/s/ John Townsend John Townsend	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2022

/s/ John Ryan, M.D., Ph.D. John Ryan, M.D., Ph.D.	Director	March 31, 2022
/s/ Sandeep Laumas, M.D. Sandeep Laumas, M.D.	Director	March 31, 2022
/s/ Brigitte Schiller, M.D. Brigitte Schiller, M.D.	Director	March 31, 2022

Exhibit 4.4

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2021, Unicycive Therapeutics, Inc. had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): (i) common stock, $0.001 par value per share ("Common Stock").

Unless the context otherwise requires, all references to "we", "us", the "Company", or "Unicycive" in this Exhibit 4.1 refer to Unicycive Therapeutics, Inc.

DESCRIPTION OF CAPITAL STOCK

The following description of our securities is intended as a summary only and is qualified in its entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the annual report on Form 10-K of which this Exhibit 4.1 is a part.

Authorized Capitalization

Our authorized capital stock consists of 200,000,000 shares of Common Stock and 10,000,000 shares of preferred stock, $0.001 par value per share ("Preferred Stock") in one or more series. As of March 29, 2022, we had outstanding 14,996,534 shares of our Common Stock and no shares of Preferred Stock.

Transfer Agent and Registrar. The transfer agent for our Common Stock is Philadelphia Stock Transfer.

Listing. Our Common Stock is traded on the Nasdaq Capital Market under the symbol "UNCY."

Common Stock

The holders of our common stock are entitled to one vote per share. Our amended and restated certificate of incorporation, as amended, does not provide for cumulative voting. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of our assets which are legally available; however, the current policy of our board of directors is to retain earnings, if any, for operations and growth. Upon our liquidation, dissolution or winding-up, holders of our common stock are entitled to share in all assets remaining after payment of all liabilities and the liquidation preferences of any of our outstanding shares of preferred stock. The holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock, which may be designated solely by action of our board of directors and issued in the future.

UNICYCIVE THERAPEUTICS, INC.
CODE OF BUSINESS CONDUCT AND ETHICS

INTRODUCTION

Unicycive Therapeutics, Inc., a Delaware corporation (the "**Company**") is committed to maintaining the highest standards of business conduct and ethics. This Code of Business Conduct and Ethics (the "**Code**") reflects the business practices and principles of behavior that support this commitment. We expect every employee, officer and director to read and understand the Code and its application to the performance of his or her business responsibilities. References in the Code to employees are intended to cover officers and, as applicable, directors.

Officers, managers and other supervisors are expected to develop in employees a sense of commitment to the spirit, as well as the letter, of the Code. Supervisors are also expected to use reasonable best efforts to ensure that all agents and contractors conform to Code standards when working for or on behalf of the Company. The compliance environment within each supervisor's assigned area of responsibility will be a factor in evaluating the quality of that individual's performance. In addition, any employee who makes an exemplary effort to implement and uphold our legal and ethical standards may be recognized for that effort in his or her performance review. Nothing in the Code alters the at-will employment policy of the Company.

This Code cannot possibly describe every practice or principle related to honest and ethical conduct. The Code addresses conduct that is particularly important to proper dealings with the people and entities with whom we interact, but reflects only a part of our commitment. From time to time we may adopt additional policies and procedures with which our employees, officers and directors are expected to comply, if applicable to them. However, it is the responsibility of each employee to apply common sense, together with his or her own highest personal ethical standards, in making business decisions where there is no stated guideline in the Code.

Action by members of your family, significant others or other persons who live in your household (referred to in the Code as "family members") also may potentially result in ethical issues to the extent that they involve the Company's business. For example, acceptance of inappropriate gifts by a family member from one of our suppliers could create a conflict of interest and result in a Code violation attributable to you. Consequently, in complying with the Code, you should consider not only your own conduct, but also that of your family members, significant others and other persons who live in your household.

You should not hesitate to ask questions about whether any conduct may violate the Code, voice concerns or clarify gray areas. Section 17 below details the compliance resources available to you. In addition, you should be alert to possible violations of the Code by others and report suspected violations, without fear of any form of retaliation, as further described in Section 17. Violations of the Code will not be tolerated. Any employee who violates the standards in the Code may be subject to disciplinary action, which, depending on the nature of the violation and the history of the employee, may range from a warning or reprimand up to and including termination of employment and, in appropriate cases, civil legal action or referral for regulatory or criminal prosecution.

1. HONEST AND ETHICAL CONDUCT

It is the policy of the Company to promote high standards of integrity by conducting our affairs in an honest and ethical manner. The integrity and reputation of the Company depends on the honesty, fairness and integrity brought to the job by each person associated with us. Unyielding personal integrity is the foundation of corporate integrity.

2. LEGAL COMPLIANCE

Obeying the law, both in letter and in spirit, is the foundation of this Code. Our success depends upon each employee operating within legal guidelines and cooperating with local, national and international authorities. We expect employees to understand the legal and regulatory requirements applicable to their business units and areas of responsibility. We hold or provide access to periodic training sessions or relevant education in order to ensure that all employees comply with the relevant laws, rules and regulations associated with their employment, including laws prohibiting insider trading (which are discussed in further detail in Section 3 below). While we do not expect you to memorize every detail of these laws, rules and regulations, we want you to be able to determine when to seek advice from others. If you do have a question in the area of legal compliance, it is important that you not hesitate to seek answers from your supervisor or the Compliance Officer (as defined in Section 17).

Disregard of the law will not be tolerated. Violation of domestic or foreign laws, rules and regulations may subject an individual, as well as the Company, to civil and/or criminal penalties. You should be aware that conduct and records, including emails, are subject to internal and external audits, and to discovery by third parties in the event of a government investigation or civil litigation. It is in everyone's best interests to know and comply with our legal and ethical obligations.

3. INSIDER TRADING

Employees who have access to confidential (or "inside") information are not permitted to use or share that information for stock trading purposes or for any other purpose except to conduct our business. All non-public information about the Company or about companies with which we do business is considered confidential information. To use material non-public information in connection with buying or selling securities, including "tipping" others who might make an investment decision on the basis of this information, is not only unethical, it is illegal. Employees must exercise the utmost care when handling material inside information.

You should consult our Insider Trading Policy for more specific information on the definition of "inside" information and on buying and selling our securities or securities of companies with which we do business.

4. RESEARCH AND DEVELOPMENT; REGULATORY COMPLIANCE

The research and development of pharmaceutical products is subject to a number of legal and regulatory requirements, including standards related to ethical research procedures and proper scientific conduct. We expect employees to comply with all such requirements.

4.1 Kickbacks, Inducements and Referrals. Various federal and state laws prohibit the solicitation or receipt, or offer or payment, of any remuneration in return for referrals of patients or business payable by a governmental health care program or third-party private payors. The application of these laws to particular business relationships is often complex. In furtherance of the foregoing, our employees responsible for business relationships with persons or entities both within and outside of the Company must take reasonable steps to ensure compliance with all applicable legal requirements. The terms and conditions of all contractual and financial arrangements of the Company shall

exclude improper inducements, kickbacks and referrals, and such arrangements may be reviewed by legal counsel when necessary. The Company, either alone or in consultation with legal counsel, shall endeavor to keep abreast of new developments relevant to such risks through regular monitoring and dissemination of new developments and guidance, continuing educational efforts and training and consultation with advisors.

4.2 False Claims. The Company shall comply with and shall cause its employees to comply with the federal False Claims Act and any other applicable federal and state laws intended to prevent and detect fraud, waste and abuse in federal or state health care programs.

4.3 Excluded Individuals and Entities. The Company does not knowingly do business with, hire or bill for services rendered by individuals or entities that are excluded or ineligible to participate in governmental health care programs or disqualified or debarred by the FDA. The Company shall screen personnel for this purpose and maintain a record of this information. Such screenings may include background checks, searches of the OIG List of Excluded Individuals and Entities and the FDA Debarment and Disqualification List, and of other government websites listing excluded individuals and entities.

4.4 Record Retention. The Company shall maintain and update as necessary a records retention system that ensures that records are maintained for the length of time required by Federal and State law, or longer if required by the Company's policies. The system, at a minimum, addresses the retention, storage and destruction of documents and provides for the retention of documents pertaining to the implementation of this Section 4.5.

5. INTERNATIONAL BUSINESS LAWS

Our employees are expected to comply with the applicable laws in all countries to which they travel, in which they operate and where we otherwise do business, including laws prohibiting bribery, corruption or the conduct of business with specified individuals, companies or countries. The fact that in some countries certain laws are not enforced or that violation of those laws is not subject to public criticism will not be accepted as an excuse for noncompliance. In addition, we expect employees to comply with U.S. laws, rules and regulations governing the conduct of business by its citizens and corporations outside the U.S.

These U.S. laws, rules and regulations, which extend to all our activities outside the U.S., include:

- The Foreign Corrupt Practices Act, which prohibits directly or indirectly giving anything of value to a government official to obtain or retain business or favorable treatment, and requires the maintenance of accurate books of account, with all company transactions being properly recorded;
- U.S. Embargoes, which generally prohibit U.S. companies, their subsidiaries and their employees from doing business with, or traveling to, certain countries subject to sanctions imposed by the U.S. government (which includes Cuba, Iran, North Korea, Sudan and Syria, among others), as well as specific companies and individuals identified on lists published by the U.S. Treasury Department;
- U.S. Export Controls, which restrict exports from the U.S. and re-exports from other countries of goods, software and technology to many countries, and prohibit transfers of U.S.-origin items to denied persons and entities; and
- Antiboycott Regulations, which prohibit U.S. companies from taking any action that has the effect of furthering or supporting a restrictive trade practice or boycott imposed by a foreign country against a country friendly to the U.S. or against any U.S. person.

If you have a question as to whether an activity is restricted or prohibited, seek assistance before taking any action, including giving any verbal assurances that might be regulated by international laws.

6. ANTITRUST

Antitrust laws are designed to protect the competitive process. These laws are based on the premise that the public interest is best served by vigorous competition and will suffer from illegal agreements or collusion among competitors. Antitrust laws generally prohibit:

- agreements, formal or informal, with competitors that harm competition or customers, including price fixing and allocations of customers, territories or contracts;
- agreements, formal or informal, that establish or fix the price at which a customer may resell a product; and
- the acquisition or maintenance of a monopoly or attempted monopoly through anti-competitive conduct.

Certain kinds of information, such as pricing, production and inventory, should not be exchanged with competitors, regardless of how innocent or casual the exchange may be and regardless of the setting, whether business or social.

Antitrust laws impose severe penalties for certain types of violations, including criminal penalties and potential fines and damages of millions of dollars, which may be tripled under certain circumstances. Understanding the requirements of antitrust and unfair competition laws of the various jurisdictions where we do business can be difficult, and you are urged to seek assistance from your supervisor or the Compliance Officer whenever you have a question relating to these laws.

7. ENVIRONMENTAL COMPLIANCE

Federal law imposes criminal liability on any person or company that contaminates the environment with any hazardous substance that could cause injury to the community or environment. Violation of environmental laws can involve monetary fines and imprisonment. We expect employees to comply with all applicable environmental laws.

It is our policy to conduct our business in an environmentally responsible way that minimizes environmental impacts. We are committed to minimizing and, if practicable, eliminating the use of any substance or material that may cause environmental damage, reducing waste generation and disposing of all waste through safe and responsible methods, minimizing environmental risks by employing safe technologies and operating procedures, and being prepared to respond appropriately to accidents and emergencies.

8. CONFLICTS OF INTEREST

We respect the rights of our employees to manage their personal affairs and investments and do not wish to impinge on their personal lives. At the same time, employees should avoid conflicts of interest that occur when their personal interests may interfere in any way with the performance of their duties or the best interests of the Company. A conflicting personal interest could result from an expectation of personal gain now or in the future or from a need to satisfy a prior or concurrent personal obligation. We expect our employees to be free from influences that conflict with the best interests of the Company or might deprive the Company of their undivided loyalty in business dealings. Even the appearance of a conflict of interest where none actually exists can be damaging and should be avoided. Whether or not a conflict of interest exists or will exist can be unclear. Conflicts of interest are prohibited unless specifically authorized as described below.

If you have any questions about a potential conflict or if you become aware of an actual or potential conflict, and you are not an officer or director of the Company, you must discuss the matter with your supervisor or the Compliance Officer. Supervisors may not authorize conflict of interest matters or make determinations as to whether a problematic conflict of interest exists without first seeking the approval of the Compliance Officer and providing the Compliance Officer with a written description of the activity. If the supervisor is involved in the potential or actual conflict, you should discuss the matter directly with the Compliance Officer. Officers and directors must seek any authorizations and determinations from the Audit Committee of the Company's Board of Directors (the "**Audit Committee**"), depending on the nature of the conflict of interest. Factors that may be considered in evaluating a potential conflict of interest are, among others:

- whether it may interfere with the employee's job performance, responsibilities or morale;
- whether the employee has access to confidential information;
- whether it may interfere with the job performance, responsibilities or morale of others within the organization;
- any potential adverse or beneficial impact on our business;
- any potential adverse or beneficial impact on our relationships with our customers or suppliers or other service providers;
- whether it would enhance or support a competitor's position;
- the extent to which it would result in financial or other benefit (direct or indirect) to the employee;
- the extent to which it would result in financial or other benefit (direct or indirect) to one of our customers, suppliers or other service providers or others who may use our products (e.g., physicians); and
- the extent to which it would appear improper to an outside observer.

Although no list can include every possible situation in which a conflict of interest could arise, the following are examples of situations that may, depending on the facts and circumstances, involve problematic conflicts of interests:

- *Employment by (including consulting for) or service on the board of a competitor, customer or supplier or other service provider.* Activity that enhances or supports the position of a competitor to the detriment of the Company is prohibited, including employment by or service on the board of a competitor. Employment by or service on the board of a customer or supplier or other service provider is generally discouraged and you must seek authorization in advance if you plan to take such a position.
- *Owning, directly or indirectly, a significant financial interest in any entity that does business, seeks to do business or competes with us* In addition to the factors described above, persons evaluating ownership in other entities for conflicts of interest will consider the size and nature of the investment; the nature of the relationship between the other entity and the Company; the employee's access to confidential information; and the employee's ability to influence the Company's decisions. If you would like to acquire a financial interest of that kind, you must seek approval in advance.

- *Soliciting or accepting gifts, favors, loans or preferential treatment from any person or entity that does business or seeks to do business with us.* See Section 12 for further discussion of the issues involved in this type of conflict.
- *Soliciting contributions to any charity or for any political candidate from any person or entity that does business or seeks to do business with us.*
- *Taking personal advantage of corporate opportunities.* See Section 9 for further discussion of the issues involved in this type of conflict.
- *Conducting our business transactions with your family member or a business in which you have a significant financial interest* Related-person transactions covered by our Related-Person Transactions Policy must be reviewed in accordance with such policy and will be publicly disclosed to the extent required by applicable laws and regulations.
- *Exercising supervisory or other authority on behalf of the Company over a co-worker who is also a family member.* The employee's supervisor and/or the Compliance Officer will consult with the Company's CEO, as necessary, to assess the advisability of reassignment.

Loans to, or guarantees of obligations of, employees or their family members by the Company could constitute an improper personal benefit to the recipients of these loans or guarantees, depending on the facts and circumstances. Some loans are expressly prohibited by law, and applicable law requires that our Board of Directors approve all loans and guarantees to employees. As a result, all loans and guarantees by the Company must be approved in advance by the Board of Directors or the Audit Committee.

9. CORPORATE OPPORTUNITIES

You may not take personal advantage of opportunities for the Company that are presented to you or discovered by you as a result of your position with us or through your use of corporate property or information, unless authorized by your supervisor, the Compliance Officer or the Audit Committee, as described in Section 17. Even opportunities that are acquired privately by you may be questionable if they are related to our existing or proposed lines of business. Participation in an investment or outside business opportunity that is directly related to our lines of business must be pre-approved. You may not use your position with us or corporate property or information for improper personal gain, nor should you compete with us in any way.

10. MAINTENANCE OF CORPORATE BOOKS, RECORDS, DOCUMENTS AND ACCOUNTS; FINANCIAL INTEGRITY; PUBLIC REPORTING

The integrity of our records and public disclosure depends upon the validity, accuracy and completeness of the information supporting the entries to our books of account. Therefore, our corporate and business records should be completed accurately and honestly. The making of false or misleading entries, whether they relate to financial results or test results, is strictly prohibited. Our records serve as a basis for managing our business and are important in meeting our obligations to customers, suppliers, creditors, employees and others with whom we do business. As a result, it is important that our books, records and accounts accurately and fairly reflect, in reasonable detail, our assets, liabilities, revenues, costs and expenses, as well as all transactions and changes in assets and liabilities. We require that:

- no entry be made in our books and records that intentionally hides or disguises the nature of any transaction or of any of our liabilities, or misclassifies any transactions as to accounts or accounting periods;
- transactions be supported by appropriate documentation;
- the terms of sales and other commercial transactions be reflected accurately in the documentation for those transactions and all such documentation be reflected accurately in our books and records;
- employees comply with our system of internal controls; and
- no cash or other assets be maintained for any purpose in any unrecorded or "off- the-books" fund.

Our accounting records are also relied upon to produce reports for our management, stockholders and creditors, as well as governmental agencies. In particular, we rely upon our accounting and other business and corporate records in preparing periodic and current reports that we file with the Securities and Exchange Commission ("**SEC**"). Securities laws require that these reports provide full, fair, accurate, timely and understandable disclosure and fairly present our financial condition and results of operations. Employees who collect, provide or analyze information for or otherwise contribute in any way in preparing or verifying these reports should strive to ensure that our financial disclosure is accurate and transparent and that our reports contain all of the information about the Company that would be important to enable stockholders and potential investors to assess the soundness and risks of our business and finances and the quality and integrity of our accounting and disclosures. In addition:

- no employee may take or authorize any action that would intentionally cause our financial records or financial disclosure to fail to comply with generally accepted accounting principles, the rules and regulations of the SEC or other applicable laws, rules and regulations;
- all employees must cooperate fully with our Accounting Department, as well as our independent public accountants and counsel, respond to their questions with candor and provide them with complete and accurate information to help ensure that our books and records, as well as our reports filed with the SEC, are accurate and complete; and
- no employee should knowingly make (or cause or encourage any other person to make) any false or misleading statement in any of our reports filed with the SEC or knowingly omit (or cause or encourage any other person to omit) any information necessary to make the disclosure in any of our reports accurate in all material respects.

Any employee who becomes aware of any departure from these standards has a responsibility to report his or her knowledge promptly to a supervisor, the Compliance Officer, the Audit Committee, or one of the other compliance resources described in Section 17.

11. FAIR DEALING

We strive to outperform our competition fairly and honestly through superior performance and not through unethical or illegal business practices. Acquiring proprietary information from others through improper means, possessing trade secret information that was improperly obtained, or inducing improper disclosure of confidential information from past or present employees of other companies is prohibited, even if motivated by an intention to advance our interests. If information is obtained by mistake that may constitute a trade secret or other confidential information of another business, or if you have any questions about the legality of proposed information gathering, you must consult your supervisor or the Compliance Officer, as further described in Section 17.

You are expected to deal fairly with our suppliers, employees and anyone else with whom you have contact in the course of performing your job. Be aware that the Federal Trade Commission Act provides that "unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce, are declared unlawful." It is a violation of the Federal Trade Commission Act to engage in deceptive, unfair or unethical practices, and to make misrepresentations in connection with sales activities.

Employees involved in procurement have a special responsibility to adhere to principles of fair competition in the purchase of products and services by selecting suppliers based exclusively on normal commercial considerations, such as quality, cost, availability, service and reputation, and not on the receipt of special favors.

12. GIFTS AND ENTERTAINMENT

Business gifts and entertainment are meant to create goodwill and sound working relationships and not to gain improper advantage with current or potential suppliers, vendors or partners or facilitate approvals from government officials. The exchange, as a normal business courtesy, of meals or entertainment (such as tickets to a game or the theatre or a round of golf) is a common and acceptable practice as long as it is not extravagant. Unless express permission is received from a supervisor, the Compliance Officer or the Audit Committee, gifts and entertainment cannot be offered, provided or accepted by any employee unless consistent with customary business practices and not excessive in value. This principle applies to our transactions everywhere in the world, even where the practice is widely considered "a way of doing business." Employees should not accept gifts or entertainment that may reasonably be deemed to affect their judgment or actions in the performance of their duties. Our customers, suppliers and the public at large should know that our employees' judgment is not for sale.

Under some statutes, such as the U.S. Foreign Corrupt Practices Act (further described in Section 5), giving anything of value to a government official to obtain or retain business or favorable treatment is a criminal act subject to prosecution and conviction. Discuss with your supervisor or the Compliance Officer any proposed

entertainment or gifts if you are uncertain about their appropriateness.

13. PROTECTION AND PROPER USE OF COMPANY ASSETS

All employees are expected to protect our assets and ensure their efficient use. Theft, carelessness and waste have a direct impact on our financial condition and results of operations. Our property, such as office supplies, computer equipment, products, laboratory supplies, and office or laboratory space are expected to be used only for legitimate business purposes, although incidental personal use may be permitted. You may not, however, use our corporate name, any brand name or trademark owned or associated with the Company or any letterhead stationery for any personal purpose.

You may not, while acting on behalf of the Company or while using our computing or communications equipment or facilities, either:

- access the internal computer system (also known as "hacking") or other resource of another entity without express written authorization from the entity responsible for operating that resource; or
- commit any unlawful or illegal act, including harassment, libel, fraud, sending of unsolicited commercial email (also known as "spam") in violation of applicable law, trafficking in contraband of any kind, or espionage.

If you receive authorization to access another entity's internal computer system or other resource, you must make a permanent record of that authorization so that it may be retrieved for future reference, and you may not exceed the scope of that authorization.

Unsolicited commercial email is regulated by law in a number of jurisdictions. If you intend to send unsolicited commercial email to persons outside of the Company, either while acting on our behalf or using our computing or communications equipment or facilities, you should contact your supervisor or the Compliance Officer for approval.

All data residing on or transmitted through our computing and communications facilities, including email and word processing documents, is the property of the Company and subject to inspection, retention and review by the Company, with or without an employee's or third party's knowledge, consent or approval, in accordance with applicable law. Any misuse or suspected misuse of our assets must be immediately reported to your supervisor or the Compliance Officer.

14. CONFIDENTIALITY

One of our most important assets is our confidential information. As an employee of the Company, you may learn of information about the Company that is confidential and proprietary. You also may learn of information before that information is released to the general public. Employees who have received or have access to confidential information should take care to keep this information confidential. Confidential information includes non-public information that might be of use to competitors or harmful to the Company or its suppliers, vendors or partners if disclosed, such as business, marketing and service plans, financial information, product development, scientific data, manufacturing, laboratory results, designs, databases, customer lists, pricing strategies, personnel data, personally identifiable information pertaining to our employees, patients or other individuals (including, for example, names, addresses, telephone numbers and social security numbers), and similar types of information provided to us by our customers, suppliers and partners. This information may be protected by patent, trademark, copyright and trade secret laws.

In addition, because we interact with other companies and organizations, there may be times when you learn confidential information about other companies before that information has been made available to the public. You must treat this information in the same manner as you are required to treat our confidential and proprietary information. There may even be times when you must treat as confidential the fact that we have an interest in, or are involved with, another company.

You are expected to keep confidential and proprietary information confidential unless and until that information is released to the public through approved channels (usually through a press release, an SEC filing or a formal communication from a member of senior management, as further described in Section 15). Every employee has a duty to refrain from disclosing to any person confidential or proprietary information about us or any other company learned in the course of employment here, until that information is disclosed to the public through approved channels. This policy requires you to refrain from discussing confidential or proprietary information with outsiders and even with other Company employees, unless those fellow employees have a legitimate need to know the information in order to perform their job duties. Unauthorized use or distribution of this information could also be illegal and result in civil liability and/or criminal penalties.

You should also take care not to inadvertently disclose confidential information. Materials that contain confidential information, such as memos, notebooks, computer disks and laptop computers, should be stored securely. Unauthorized posting or discussion of any information concerning our business, information or prospects on the Internet is prohibited. You may not discuss our business, information or prospects in any "chat room," regardless of whether you use your own name or a pseudonym. Be cautious when discussing sensitive information in public places like elevators, airports, restaurants and "quasi-public" areas within the Company, or in and around the Company's facilities. All Company emails, voicemails and other communications are presumed confidential and should not be forwarded or otherwise disseminated outside of the Company, except where required for legitimate business purposes.

In addition to the above responsibilities, if you are handling information protected by any privacy policy published by us, then you must handle that information in accordance with the applicable policy.

15. MEDIA/PUBLIC DISCUSSIONS

It is our policy to disclose material information concerning the Company to the public only through specific limited channels to avoid inappropriate publicity and to ensure that all those with an interest in the Company will have equal access to information. All inquiries or calls from the press and financial analysts should be referred to our Chief Executive Officer. We have designated our Chief Executive Officer as our official spokesperson for questions concerning the financial performance, strategic direction or operating performance of the Company, and operational issues such a research and development, regulatory developments, sales and marketing, etc. Unless a specific exception has been made by the Chief Executive Officer, he or she is the only person who may communicate with the press on behalf of the Company. You also may not provide any information to the media about us off the record, for background, confidentially or secretly, including, without limitation, by way of postings on internet websites, chat rooms or "blogs".

16. WAIVERS

Any waiver of this Code for executive officers (including, where required by applicable laws, our principal executive officer, principal financial officer, principal accounting officer or controller (or persons performing similar functions)) or directors may be authorized only by our Board of Directors or, to the extent permitted by the rules of The Nasdaq Stock Market, a committee of the Board and will be disclosed as required by applicable laws, rules and regulations.

17. COMPLIANCE STANDARDS AND PROCEDURES

Compliance Resources

To facilitate compliance with this Code, we have implemented a program of Code awareness, training and review that is part of our broader compliance programs overseen by our Audit Committee. We have established the position of Compliance Officer, which shall initially be held by the Company's Chief Executive Officer, to oversee this program. The Compliance Officer is a person to whom you can address any questions or concerns related to this Code or any other matters relating to legal or regulatory compliance. In addition to fielding questions or concerns with respect to potential violations of this Code or any other matters relating to legal or regulatory compliance, the Compliance Officer is responsible for:

- investigating possible violations of the Code;
- training new employees in Code policies;
- conducting annual training sessions to refresh employees' familiarity with the Code;
- distributing copies of the Code annually via e-mail to each employee with a reminder that each employee is responsible for reading, understanding and complying with the Code;
- updating the Code as needed and alerting employees to any updates, with appropriate approval of the Audit Committee, to reflect changes in the law, the Company's operations and in recognized best practices, and to reflect the Company's experience;

- overseeing the Company's compliance program and reporting to the Audit Committee material matters that may arise relating to the Company's legal and regulatory compliance efforts; and
- otherwise promoting an atmosphere of responsible and ethical conduct.

Your most immediate resource for any matter related to the Code is your supervisor. He or she may have the information you need, or may be able to refer the question to another appropriate source. There may, however, be times when you prefer not to go to your supervisor. In these instances, you should feel free to discuss your concern with the Compliance Officer. If you are uncomfortable speaking with the Compliance Officer because he or she works in your department or is one of your supervisors, please contact the Chief Executive Officer.

Clarifying Questions and Concerns; Reporting Possible Violations

If you encounter a situation or are considering a course of action and its appropriateness is unclear, discuss the matter promptly with your supervisor or the Compliance Officer; even the appearance of impropriety can be very damaging and should be avoided.

If you are aware of a suspected or actual violation of Code standards by others, you have a responsibility to report it. You are expected to promptly provide a compliance resource with a specific description of the violation that you believe has occurred, including any information you have about the persons involved and the time of the violation. Whether you choose to speak with your supervisor or the Compliance Officer, you should do so without fear of any form of retaliation. We will take prompt disciplinary action against any employee who retaliates against you, up to and including termination of employment.

Supervisors must promptly report any complaints or observations of Code violations to the Compliance Officer. If you believe your supervisor has not taken appropriate action, you should contact the Compliance Officer directly. The Compliance Officer will investigate all reported possible Code violations promptly and with the highest degree of confidentiality that is possible under the specific circumstances. Neither you nor your supervisor may conduct any preliminary investigation, unless authorized to do so by the Compliance Officer. Your cooperation in the investigation will be expected. As needed, the Compliance Officer will consult with, outside legal counsel and/or the Audit Committee. It is our policy to employ a fair process by which to determine violations of the Code.

With respect to any complaints or observations of Code violations, including, but not limited to matters that may involve accounting, internal accounting controls and auditing concerns, the Compliance Officer shall promptly inform the chair of the Audit Committee, and the Audit Committee or such other persons as the Audit Committee determines to be appropriate under the circumstances shall be responsible for supervising and overseeing the inquiry and any investigation that is undertaken. In addition, any matters involving accounting, internal accounting controls and auditing concerns that are reported shall be routed to both the Compliance Officer and the Audit Committee.

If any investigation indicates that a violation of the Code has probably occurred, we will take such action as we believe to be appropriate under the circumstances. If we determine that an employee is responsible for a Code violation, he or she will be subject to disciplinary action up to, and including, termination of employment and, in appropriate cases, civil legal action or referral for regulatory or criminal prosecution. Appropriate action may also be taken to deter any future Code violations.

Effective May 2021

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-259476 on Form S-8 of our report dated March 31, 2022, with respect to the financial statements of Unicycive Therapeutics, Inc. as of December 31, 2021 and 2020 and for each of the two years in the period ended December 31, 2021, included in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
March 31, 2022

Exhibit 31.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Shalabh Gupta, M.D., certify that:

(1) I have reviewed this Form 10-K of Unicycive Therapeutics, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

By: */s/ Shalabh Gupta, M.D.*
Shalabh Gupta, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Townsend, certify that:

(1) I have reviewed this Form 10-K of Unicycive Therapeutics, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the Registrant’s internal control over financial reporting that occurred during the Registrant’s most recent fiscal quarter (the Registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant’s internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

By: */s/ John Townsend*
John Townsend
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Unicycive Therapeutics, Inc. (the "Company") on Form 10-K for the twelve month period ended December 31, 2021, as filed with the Securities and Exchange Commission on March 31, 2022 (the "Report"), I, Shalabh Gupta, M.D., Chief Executive Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for the periods presented in the Report.

By: */s/ Shalabh Gupta, M.D.*
Shalabh Gupta, M.D.
Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Unicycive Therapeutics, Inc. (the "Company") on Form 10-K for the twelve month period ended December 31, 2021, as filed with the Securities and Exchange Commission on March 31, 2022 (the "Report"), I, John Townsend, Chief Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for the periods presented in the Report.

By: */s/ John Townsend*
John Townsend
Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be furnished to the Securities and Exchange Commission or its staff upon request.