As filed with the Securities and Exchange Commission on May 21, 2021.

Registration Statement No. 333-

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

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

UNICYCIVE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**81-3638692**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

5150 El Camino Real, Suite A-32
Los Altos, CA 94022
(650) 351-4495
(Address and telephone number of registrant's principal executive offices)

Shalabh Gupta, M.D.
Chief Executive Officer
Unicycive Therapeutics, Inc.
5150 El Camino Real, Suite A-32
Los Altos, CA 94022
(650) 351-4495
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Jeffrey J. Fessler
Alexander T. Yarbrough
Sheppard, Mullin, Richter & Hampton LLP
30 Rockefeller Plaza
New York, NY 10112
Telephone: (212) 653-8700
Facsimile: (212) 653-8701

Ralph V. De Martino
Cavas S. Pavri
Schiff Hardin LLP
901 K Street NW, Suite 700
Washington, DC 20001
Telephone: (202) 778-6400
Facsimile: (202) 778-6460

Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price [1]	Amount of Registration Fee [2]
Common Stock, par value $0.001 per share	$ 34,500,000	$ 3,763.95
Underwriters' Warrants [3]		
Common stock underlying underwriters' warrants [4]	$ 1,800,000	196.38
Total	$ 36,300,000	3,960.33

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act"). Includes shares of common stock that the underwriters have the option to purchase to cover over-allotments, if any.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price of the securities registered hereunder to be sold by the registrant.

(3) No separate registration fee is required pursuant to Rule 457(g) under the Securities Act.

(4) The registrant has agreed to issue, upon the closing of this offering, warrants to Roth Capital Partners, LLC entitling it to purchase a number of shares of common stock equal to 5% of the aggregate shares of common stock sold in this offering. The exercise price of the warrants will be equal to 120% of the public offering price of the common stock offered hereby.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MAY 21, 2021

Shares

Common Stock

This is the initial public offering of Unicycive Therapeutics, Inc. We are offering shares of our common stock. No public market currently exists for our stock. We anticipate that the initial public offering price will be between $ and $ per share.

We have applied to list the shares of our common stock on the Nasdaq Capital Market under the symbol "UNCY."

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 6.

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

	Per Share	Total
Price to the public	$	$
Underwriting discounts and commissions	$	$
Proceeds to us (before expenses)[1]	$	$

(1) We refer you to "Underwriting" beginning on page 92 of this prospectus for additional information regarding underwriting compensation.

We have granted the underwriters a 45-day option to purchase up to additional shares at the initial public offering price, less the underwriting discount.

The underwriters expect to deliver the shares on or about ,2021.

Sole Book-Running Manager

Roth Capital Partners

Lead Manager

KINGSWOOD CAPITAL MARKETS
division of Benchmark Investments, Inc.

The date of this prospectus is , 2021

TABLE OF CONTENTS

We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give to you. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

You should rely only on the information contained in this prospectus. No dealer, salesperson or other person is authorized to give information that is not contained in this prospectus. This prospectus is not an offer to sell nor is it seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of these securities.

All trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

PROSPECTUS SUMMARY

The following summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. It does not contain all the information that may be important to you and your investment decision. You should carefully read this entire prospectus, including the matters set forth under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our financial statements and related notes included elsewhere in this prospectus. In this prospectus, unless context requires otherwise, references to "we," "us," "our," "Unicycive" or "Unicycive Therapeutics," or the "Company" refer to Unicycive Therapeutics, Inc.

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 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 with CKD stage 3-5, and around 400 thousand patients with end-stage renal disease (ESRD) have hyperphosphatemia. In the European Union (EU), around 20 million (approximately 8%) adults have CKD, more than 1 million CKD stage 3-5 patients, and approximately 180 thousand patients with ESRD have hyperphosphatemia. The number of patients with ESRD is increasing steadily and is projected to reach between 971,000 and 1,259,000 in 2030.

AKI is a sudden episode of kidney failure or kidney damage (within the first 90 days of injury). After 90 days, the patient is considered to have progressed into CKD. AKI affects over 2 million 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.

Amended and Restated Certificate of Incorporation

Immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, we will file an Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware, which, among other things, will effectuate a one-for- (1:) reverse stock split (the "Reverse Stock Split") of our common stock without any change to its par value. No fractional shares will be issued in connection with the Reverse Stock Split as all fractional shares will be rounded up to the next whole share. See "Description of Capital Stock" on page 85 for additional details on our Amended and Restated Certificate of Incorporation.

Amended and Restated Bylaws

Our board of directors has authorized the adoption of Amended and Restated Bylaws to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. See "Description of Capital Stock" on page 85 for additional details on the provisions included in our Amended and Restated Bylaws.

Corporate Information

We were incorporated as a Delaware corporation on August 18, 2016. Our principal executive offices are located at 5150 El Camino Real, Suite A-32, Los Altos, CA 94022 and our telephone number is (650) 351-4495. Our website address is *http://www.unicycive.com*. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common shares.

Implications of Being an Emerging Growth Company

As a company with less than $1.07 billion in revenues during our last fiscal year, we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act ("JOBS Act") enacted in 2012. As an emerging growth company, we expect to take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include, but are not limited to:

- being permitted to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended ("Sarbanes-Oxley Act");
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration 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.

We may use these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

THE OFFERING

Common stock offered by us	Shares
Common stock to be outstanding immediately after this offering	shares (shares if the underwriters exercise their over-allotment option in full).
Over-allotment Option to purchase additional shares	The underwriters have an option for a period of 45 days to purchase up to an additional shares of our common stock.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $, or approximately $ if the underwriters exercise their over-allotment option in full, at an assumed initial public offering price of $ per share, the midpoint of the range set forth on the cover page of this prospectus, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to complete pre-clinical studies, including toxicology studies as recommended by the FDA, in connection with a New Drug Application (NDA) filing for Renazorb with the FDA. In addition, we plan to use proceeds to advance UNI 494 for pre-clinical development and the completion of Phase 1 and Phase 2 clinical studies for a potential IND filing in 2022. We also plan to use the remainder of the net proceeds for general and corporate purposes, including, but not limited to, hiring additional management and conducting market research and other commercial planning. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products, however, we have no current commitments or obligations to do so. See "Use of Proceeds" for a more complete description of the intended use of proceeds from this offering.
Underwriters' warrants	Upon the closing of this offering, we will issue to Roth Capital Partners, LLC, as the representative of the underwriters in this offering, warrants entitling it to purchase a number of shares of common stock equal to 5% of the shares of common stock sold in this offering at an exercise price equal to the public offering price of the common stock in this offering. The warrant will be exercisable at any time, and from time to time, in whole or in part, during the period commencing 180 days from the commencement of sales in this offering, and expiring five years from the commencement of sales in this offering. The warrant is also exercisable on a cashless basis.
Lockups	We have agreed, subject to certain exceptions and without the approval of the representative of the underwriters, not to offer, issue, sell, contract to sell, encumber, grant any option for the sale of or otherwise dispose of any of our securities for a period of six months following the closing of the offering of the shares. Our directors, executive officers and certain stockholders have agreed with the underwriters not to offer for sale, issue, sell, contract to sell, pledge or otherwise dispose of any of our common stock or securities convertible into common stock for a period of six months commencing on the closing date of this offering. See "Underwriting" beginning on page 92.
Risk factors	See "Summary of Risk Factors" and "Risk Factors" on page 4 and 6, respectively, and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed Nasdaq Capital Market symbol	"UNCY"

The number of shares of our common stock to be outstanding after this offering is based on 37,682,715 shares of our common stock outstanding as of May 19, 2021 and the conversion of outstanding convertible notes into shares of common stock, and excludes:

- 2,875,501 shares of common stock issuable upon exercise of outstanding options as of that date having a weighted average exercise price of $0.70 per share;
- 75,000 shares of our common stock reserved for future issuance under our 2018 Equity Incentive Plan;
- 5,577,000 shares of our common stock reserved for future issuance under our 2019 Stock Option Plan, and
- 5,600,000 shares of our common stock reserved for future issuance under our 2021 Stock Option Plan.

Except as otherwise indicated herein, all information in this prospectus assumes:

- no exercise by the underwriters of their option to purchase an additional shares of common stock.
- a 1-for- reverse stock split of our common stock to be completed immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, pursuant to which (i) every shares of outstanding common stock was decreased to one share of common stock, (ii) the number of shares of common stock for which each outstanding warrant or option to purchase common stock is exercisable was proportionally decreased on a 1-for- basis, and (iii) the exercise price of each outstanding warrant or option to purchase common stock was proportionately increased on a 1-for- basis, (the "Reverse Stock Split").

SUMMARY OF RISK FACTORS

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 Related to our Financial Position and Need for Capital

- we have generated no revenue to date and our future profitability is uncertain;
- 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;
- our financial situation creates doubt whether we will continue as a going concern;
- 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; and
- 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 Related to Our Business

- the approval process of the FDA is lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our current product candidates and future product candidates we intend to develop, our business will be substantially harmed;
- we may encounter substantial delays in completing our clinical studies which in turn will require additional costs, or we may fail to demonstrate adequate safety and efficacy to the satisfaction of applicable regulatory authorities;
- if we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our product candidates and our ability to generate revenue will be impaired;
- even if our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success;
- we may be adversely affected by the ongoing coronavirus (COVID-19) pandemic;
- we will need to grow the size of our organization in the future, and we may experience difficulties in managing this growth;
- 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; and
- 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.

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; and
- Healthcare regulations in the United States are subject to continuous reform.

Risks Related to Owning our Common Stock and this Offering

- an active trading market for our common stock may not develop, and you may not be able to sell your common stock at or above the initial public offering price;
- the price of our common stock may fluctuate substantially;
- 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;
- you will incur immediate dilution as a result of this offering;
- we do not expect to pay dividends in the foreseeable future; and
- our Amended and Restated Certificate of Incorporation, to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, contains certain exclusive forum provisions.

SUMMARY FINANCIAL DATA

The following tables set forth our summary financial data as of the dates and for the periods indicated. We have derived the summary statement of operations data for the years ended December 31, 2019 and 2020 from our audited financial statements and for the three months ended March 31, 2020 and 2021 from our unaudited financial statements included elsewhere in this prospectus. The following summary financial data should be read with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes and other information included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results to be expected in the future.

Statement of Operations Data:
(in thousands)

	Years Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
Operating costs and expenses			(unaudited)	(unaudited)
Research and development	$ 795	$ 1,015	$ 148	$ 450
General and administrative	1,168	1,005	194	281
Total operating costs and expenses	1,963	2,020	342	731
Net loss	$ (2,165)	$ (2,264)	$ (344)	$ (964)
Net loss per common share – basic and diluted[(1)]	$ (0.06)	$ (0.06)	$ (0.01)	$ (0.03)
Weighted average common shares outstanding – basic and diluted[(1)]	34,915,828	36,548,372	36,387,830	36,878,327

(1) See Note 11 to our financial statements for an explanation of the method used to compute basic and diluted net loss per share.

Balance Sheet Data:

(in thousands)

	March 31, 2021		
	Actual	Pro Forma[(1)]	Pro Forma, As Adjusted[(2)(3)]
	(unaudited)	(unaudited)	(unaudited)
Cash	$ 147	$	$
Working capital (deficit)	(3,402)		
Total assets	513		
Total liabilities	(3,915)		
Accumulated deficit	(6,886)		
Total stockholders' equity (deficit)	(3,402)		

(1) On a pro forma basis to reflect the conversion of convertible notes in the aggregate principal amount of $2,388,000 issued between July 2020 and through May 2021 into an aggregate of shares of common stock assuming an initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus);

(2) On a pro forma as adjusted basis to give further effect to our issuance and sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us,

(3) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity (deficit) by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of shares in the number of shares offered by us at the assumed initial public offering price per share, the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, working capital, total assets and total stockholders' equity (deficit) by approximately $.

RISK FACTORS

An investment in our common stock involves a high degree of risk. Before making an investment decision, you should give careful consideration to the following risk factors, in addition to the other information included in this prospectus, including our financial statements and related notes, before deciding whether to invest in shares of our common stock. The occurrence of any of the adverse developments described in the following risk factors could materially and adversely harm our business, financial condition, results of operations or prospects. In that case, the 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, 2019 and 2020 and for the three months ended March 31, 2020 and 2021 was $.2.2 million, $2.3 million, $.3 million and $1.0 million, respectively, and our accumulated deficit as of March 31, 2021 was $6.9 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. We expect the net proceeds of this offering to be sufficient to satisfy our capital requirements for a period of 12 months from the date of this prospectus. Accordingly, we believe that we will need to raise substantial additional capital 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.

There is substantial doubt about our ability to continue as a going concern.

As of December 31, 2019, December 31, 2020, and March 31, 2021, we had cash of $15,000, less than $1,000, and $147,000, respectively. In addition, we had current liabilities of approximately $3.9 million as of March 31, 2021. We expect our existing cash as of March 31, 2021 together with proceeds from this offering will enable us to fund our operating expenses and capital expenditure requirements for at least 12 months from the date of this prospectus. In the event that we are unable to obtain additional financing, we may be unable to continue as a going concern. There is no guarantee that we will be able to secure additional financing, including in connection with this offering. Changes in our operating plans, our existing and anticipated working capital needs, costs related to legal proceedings we might become subject to in the future, the acceleration or modification of our development activities, any near-term or future expansion plans, increased expenses, potential acquisitions or other events may further affect our ability to continue as a going concern. Similarly, the report of our independent registered public accounting firm on our financial statements as of and for the year ended December 31, 2020 includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in us.

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 March 31, 2021, we had 1 full-time employee and 7 consultants. 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 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, 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, Shalabh Gupta, is also the Chief Executive Officer of Globavir and may not commit his full time to our affairs, which may result in a conflict of interest in allocating his time between our business and the other business. Similarly, certain members of our Board of Directors are members of the board of directors of Globavir and may not commit their full time to our affairs, which may result in a conflict of interest in allocating their time between our business and the other business. Furthermore, neither our Chief Executive Officer, our executive team, nor our directors are obligated to contribute any specific number of his hours per week to our affairs. If other business affairs require our Chief Executive Officer and/or directors to devote more amounts of time to other affairs, including the business of Globavir, it could limit their ability to devote time to our affairs and could have a negative impact on our ability to implement our plan of operation.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

In addition, disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third-party expresses interest in an area under a license that we are not pursuing, under the terms of certain of our license agreements, we may be required to sublicense rights in that area to a third party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Healthcare Compliance and Other Regulations

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

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

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing information to customers;

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

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

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

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

Healthcare Reform in the United States.

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

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- implementation of the federal physician payment transparency requirements, sometimes referred to as the "Physician Payments Sunshine Act";

- a licensure framework for follow-on biologic products;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

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

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

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

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

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

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

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

Some of the provisions of the ACA have yet to be implemented, and there have been legal and political challenges to certain aspects of the ACA. The former Trump administration issued certain executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Congress may consider other legislation to repeal or replace elements of the ACA.

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

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

Individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm a pharmaceutical manufacturer's business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce ultimate demand for certain products or put pressure product pricing, which could negatively affect a pharmaceutical manufacturer's business, results of operations, financial condition and prospects.

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

In addition, given recent federal and state government initiatives directed at lowering the total cost of healthcare, the Biden administration, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and biologics and the reform of the Medicare and Medicaid programs. For example, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. Further, in July 2020, former President Trump issued a number of executive orders that are intended to lower the costs of prescription drug products including one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for discounts for plans, pharmacies, and pharmaceutical benefit managers. No assurance can be given whether these orders will remain in effect under the Biden administration.

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

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

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

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

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Owning our Common Stock and this Offering

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

Prior to the consummation of this offering, there has been no public market for our common stock. An active trading market for shares of our common stock may never develop or be sustained following this offering. If an active trading market does not develop, you may have difficulty selling your shares of common stock at an attractive price, or at all. The price for our common stock in this offering will be determined by negotiations between us and the underwriters, and it may not be indicative of prices that will prevail in the open market following this offering. Consequently, you may not be able to sell your common stock at or above the initial public offering price or at any other price or at the time that you would like to sell. An inactive market may also impair our ability to raise capital by selling our common stock, and it may impair our ability to attract and motivate our employees through equity incentive awards and our ability to acquire other companies, products or technologies by using our common stock as consideration.

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 prospectus, 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 attract new customers;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our product candidates or any future clinical trials we may conduct;
- changes in the development status of our product candidates;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our planned pre-clinical and clinical trials;

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

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

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this initial public offering, including for any of the currently intended purposes described in the section entitled “Use of Proceeds.” Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management may not apply our cash from this offering in ways that ultimately increase the value of any investment in our securities or enhance stockholder value. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our cash in ways that enhance stockholder value, we may fail to achieve expected financial results, which may result in a decline in the price of our shares of common stock, and, therefore, may negatively impact our ability to raise capital, invest in or expand our business, acquire additional products or licenses, commercialize our product, or continue our operations.

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 after the closing of this offering, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

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.

Following this offering, our directors, executive officers and principal stockholders, and their respective affiliates, will beneficially own approximately % of our outstanding shares of common stock. As a result, these stockholders, acting together, would 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, would 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.

You will incur immediate dilution as a result of this offering.

If you purchase common stock in this offering, you will pay more for your shares than the net tangible book value of your shares. As a result, you will incur immediate dilution of $ per share, representing the difference between the assumed initial public offering price of $ per share (the midpoint of the range on the cover of this prospectus) and our pro forma net tangible book value per share as of March 31, 2021 of $. Accordingly, should we be liquidated at our book value, you would not receive the full amount of your investment.

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 this offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We may be at risk of securities class action litigation.

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

There is no guarantee that our common stock will be listed on Nasdaq.

We have applied to have our shares of common stock listed on the Nasdaq Capital Market. Upon completion of this offering, we believe that we will satisfy the listing requirements and expect that our common stock will be listed on the Nasdaq Capital Market. Such listing, however, is not guaranteed. If the application is not approved, we may seek to have our common stock quoted on the OTCQB operated by the OTC Markets Group, Inc. Even if such listing is approved, there can be no assurance any broker will be interested in trading our common stock. Therefore, it may be difficult to sell any shares you purchase in this offering if you desire or need to sell them.

Our amended and restated certificate of incorporation ("Amended and Restated Certificate of Incorporation") and our amended and restated bylaws (the "Amended and Restated Bylaws"), to be effective upon completion of this offering, 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, each to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, 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, to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, 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, to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, 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 to be effective upon completion of this offering, 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 or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our Amended and Restated Certificate of Incorporation, to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, 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 such 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, 2019 and 2020, 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. 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.

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve risks and uncertainties. You should not place undue reliance on these forward-looking statements. All statements other than statements of historical facts contained in this prospectus are forward-looking statements. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. In some cases, you can identify these forward-looking statements by terms such as "anticipate," "believe," "continue," "could," "depends," "estimate," "expects," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms or other similar expressions, although not all forward-looking statements contain those words. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements include, but are not limited to, statements concerning the following:

- 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 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.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

INDUSTRY AND MARKET DATA

This prospectus contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. We obtained the industry and market data in this prospectus from our own research as well as from industry and general publications, surveys and studies conducted by third parties. These data involve a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty, including those discussed in "Risk Factors." We caution you not to give undue weight to such projections, assumptions and estimates. Further, industry and general publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that these publications, studies and surveys are reliable, we have not independently verified the data contained in them. In addition, while we believe that the results and estimates from our internal research are reliable, such results and estimates have not been verified by any independent source.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately $ million, based on an assumed initial public offering price of $ per share, the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that the net proceeds from this offering will be approximately $ million.

We intend to use the net proceeds from this offering as follows:

- toxicology and chemistry studies in support of an NDA filing for Renazorb, which we estimate to be approximately $2.0 million;
- milestone payment if NDA for Renazorb is approved, which we estimate to be approximately $5.0 million;
- pre-clinical studies of UNI 494 in support of potential IND filing in 2022, which we estimate to be approximately $2.0 million;
- completion of Phase I and Phase 2 clinical trials with UNI 494, which we estimate to be approximately $7 million; and
- the remainder of the net proceeds will be used for general and corporate purposes, including, but not limited to, hiring additional management and conducting market research and other commercial planning.

A $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease the net proceeds from this offering by approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions.

This expected use of the net proceeds from this offering and our existing cash represents our intentions based upon our current plans, financial condition and business conditions. Predicting the cost necessary to develop product candidates can be difficult and the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development and commercialization efforts, the status of and results from clinical trials, any collaborations that we may enter into with third parties for our product candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering and our existing cash.

In the ordinary course of our business, we expect to from time to time evaluate the acquisition of, investment in or in-license of complementary products, technologies or businesses, and we could use a portion of the net proceeds from this offering for such activities. We currently do not have any agreements, arrangements or commitments with respect to any potential acquisition, investment or license.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and government securities.

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.

CAPITALIZATION

The following table sets forth our cash and capitalization as of March 31, 2021:

- on an actual basis;
- on a pro forma basis to give effect to the conversion of $2,388,000 of principal amount and accrued interest of outstanding notes into an aggregate of shares of common stock upon the closing of this offering based upon an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of shares of our common stock included in the shares of common stock being sold in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and our estimated offering expenses.

(in thousands, except share and per share data)	Actual (unaudited)	Pro Forma (unaudited)	Pro Forma, As Adjusted (unaudited) [1]
Cash	$ 147	$	$
Loan from stockholder	695		
Convertible notes	2,790		
Stockholders' deficit:			
Preferred stock, par value $0.001 per share; 10,000,000 shares authorized, no issued and outstanding, actual; no shares authorized, issued and outstanding	-		
Common stock, par value $0.001 per share; 200,000,000 shares authorized, 37,615,632 shares issued and outstanding, actual; shares authorized, shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	38		
Additional paid-in capital	3,446		
Accumulated deficit	(6,886)		
Total stockholders' deficit	(3,402)		
Total capitalization	$ 230	$	$

(1) A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, total stockholders' equity and total capitalization by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. An increase (decrease) of shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, total stockholders' equity and total capitalization by $ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions.

The number of shares of our common stock to be outstanding after this offering is based on 37,615,632 shares of our common stock outstanding as of March 31, 2021 and excludes the following:

- 2,942,584 shares of common stock issuable upon exercise of outstanding options as of that date having a weighted average exercise price of $0.68 per share.
- 75,000 shares of common stock reserved for future issuance under our 2018 Equity Incentive Plan; and
- 5,577,000 shares of common stock reserved for future issuance under our 2019 Stock Option Plan.

Except as otherwise indicated herein, all information in this prospectus assumes:

- a one-for- (1:) reverse stock split of our common stock to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part; and
- no exercise of the outstanding options or warrants described above.

DILUTION

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

As of March 31, 2021 we had a historical net tangible book value (deficit) of $(3.4 million), or ($0.09) per share of common stock, based on 37,615,632 shares of common stock outstanding at March 31, 2021. Our historical net tangible book value per share is the amount of our total tangible assets less our total liabilities at March 31, 2021, divided by the number of shares of common stock outstanding at March 31, 2021.

After giving effect to the conversion of $2,388,000 of principal amount and accrued interest of outstanding notes into an aggregate of shares of common stock upon the closing of this offering based upon an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, our pro forma net tangible book value at March 31, 2021 would have been $ million, or $ per share of common stock.

After giving further effect to the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at March 31, 2021 would have been $ million, or $ per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to existing stockholders and immediate dilution of $ per share to new investors purchasing shares of common stock in this offering.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$
Pro forma net tangible book value per share as of March 31, 2021	$	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors in this offering		
Pro forma as adjusted net tangible book value per share immediately after this offering		
Dilution per share to new investors in this offering		$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value after this offering by $ per share and the dilution to new investors purchasing common stock in this offering by $ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discount and commissions. An increase of shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value after this offering by $ per share and decrease the dilution to new investors purchasing common stock in this offering by $ per share, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions. A decrease of shares in the number of shares offered by us would decrease the pro forma as adjusted net tangible book value after this offering by $ per share and increase the dilution to new investors purchasing common stock in this offering by $ per share, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions.

If the underwriters exercise their option to purchase additional shares in full, the pro forma as adjusted net tangible book value per share after giving effect to the offering would be $ per share. This represents an increase in pro forma as adjusted net tangible book value of $ per share to existing stockholders and dilution in pro forma as adjusted net tangible book value of $ per share to new investors.

The number of shares of our common stock to be outstanding after this offering is based on 37,615,632 shares of our common stock outstanding as of March 31, 2021 and excludes the following:

- 2,942,584 shares of common stock issuable upon exercise of outstanding options as of that date having a weighted average exercise price of $0.68 per share.
- 75,000 shares of common stock reserved for future issuance under our 2018 Equity Incentive Plan; and
- 5,577,000 shares of common stock reserved for future issuance under our 2019 Stock Option Plan.

Except as otherwise indicated herein, all information in this prospectus assumes:

- a one-for- (1:) reverse stock split of our common stock to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part; and
- no exercise of the outstanding options or warrants described above.

The following table summarizes, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us, the total consideration paid or to be paid, and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares Purchased		Total Consideration		Average Price
	Number	Percentage	Amount	Percentage	Per Share
Existing stockholders			$		$
New investors					$
Total			$		

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by $ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by $ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease of shares, would decrease the percentage of total consideration paid by new investors by percentage points, assuming no change in the assumed initial public offering price.

The table above assumes no exercise of the underwriters' over-allotment option in this offering. If the underwriters' over-allotment option is exercised in full, the number of common shares held by new investors purchasing common stock in this offering would be increased to % of the total number of shares of common stock outstanding after this offering, and the number of shares held by existing stockholders would be reduced to % of the total number of shares of common stock outstanding after this offering.

To the extent that stock options or warrants are exercised or convertible debt is converted, we issue new stock options under our equity incentive plan, or we issue additional common stock in the future, there will be further dilution to investors participating in this offering. In addition, if we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this prospectus. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this prospectus. See "Information Regarding Forward-Looking Statements." All amounts in this report are in U.S. dollars, unless otherwise noted.

Overview

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

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

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

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

Since our formation we have devoted substantially all of our resources to developing our product candidates. We have incurred significant operating losses to date. Our net losses were $2.2 million and $2.3 million for the years ended December 31, 2019 and 2020, respectively, and $0.3 million and $1.0 million for the three months ended March 31, 2020 and 2021, respectively. As of March 31, 2021, we had an accumulated deficit of $6.9 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, upon the completion of this offering, 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. We believe that our current available cash will not be sufficient to fund our planned expenditures and meet our obligations through the end of the second quarter 2021, and there is substantial doubt about our ability to continue as a going concern for one year after the date that these financial statements are available to be issued.

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 organization, 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 $1,098,000. 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 convert into common stock upon consummation of this offering at 70% of the public offering price per share.

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 1,348,750 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 (20th) anniversary of the Closing Date of the Renazorb Purchase Agreement.

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.

Results of Operations

Comparison of the Three Months Ended March 31, 2020 and 2021

The following table summarizes our results of operations for the periods indicated (in thousands):

	Three Months Ended March 31,			
	2020	2021	Change	% Change
	(unaudited)	(unaudited)		
Operating expenses:				
Research and development	$ 148	$ 450	$ 302	204%
General and administrative	194	281	87	45%
Total operating expenses	342	731	389	114%
Loss from operations	(342)	(731)	(389)	114%
Other income (expenses):				
Interest expense	(2)	(252)	(250)	12,500%
Gain on extinguishment of debt	-	19	19	100%
Total other income (expenses)	(2)	(233)	(231)	11,550%
Net loss	$ (344)	$ (964)	$ (620)	180%

Research and Development Expenses

Research and development expenses increased by approximately $302,000, or 204%, from the three months ended March 31, 2020 to the three months ended March 31, 2021. The increase in research and development expenses was primarily due to an increase in stock compensation expense of $168,000. In addition, development costs increased $118,000 due to product formulation and consulting services in the current period, and labor costs increased $16,000.

General and Administrative Expenses

General and administrative expenses increased by $87,000, or 45%, from the three months ended March 31, 2020 to the three months ended March 31, 2021 primarily due to an increase in accounting and professional services costs of $80,000. In addition, labor costs increased $19,000 and stock compensation costs increased $4,000. These increases were partially offset by a decrease in travel and other expenses of $16,000.

Other Income (Expenses)

Other income (expenses) increased by $231,000, or 11,550% from the three months ended March 31, 2020 to the three months ended March 31, 2021. The increase was due primarily to interest expense on outstanding convertible notes and was partially offset by a gain on extinguishment of debt for our Paycheck Protection Program loan of $19,000.

Comparison of the Years Ended December 31, 2019 and 2020

The following table summarizes our results of operations for the periods indicated (in thousands):

	Years Ended December 31,			
	2019	2020	Change	% Change
Operating expenses:				
Research and development	$ 795	$ 1,015	$ 220	28%
General and administrative	1,168	1,005	(163)	(14%)
Total operating expenses	1,963	2,020	57	3%
Loss from operations	(1,963)	(2,020)	(57)	3%
Other income (expenses):				
Interest expense	(139)	(244)	(105)	76%
Other Expenses - Loss on debt conversion	(63)	-	63	(100%)
Total other income (expenses)	(202)	(244)	(42)	21%
Net loss	$ (2,165)	$ (2,264)	$ (99)	5%

Research and Development Expenses

Research and development expenses increased by approximately $220,000, or 28%, from the year ended December 31, 2019 to the year ended December 31, 2020. The increase in research and development expenses was primarily due to an increase in stock compensation expense of $160,000. Labor costs increased $121,000, and development costs increased $59,000 during the current year ended December 31, 2020. The increases were partially offset by decreases in our anti-dilution expenses associated with our agreement with Spectrum Pharmaceuticals of $41,000 and decreases in consulting and other costs of $79,000.

General and Administrative Expenses

General and administrative expenses decreased by $163,000, or 14%, from the year ended December 31, 2019 to the year ended December 31, 2020 primarily due to the decrease in our service agreement with Globavir of $480,000. In addition, travel, seminar costs and other expenses decreased $115,000. These decreases were partially offset by increases in financial, accounting, and professional services of $258,000, labor costs of $126,000, and stock compensation expenses of $48,000.

Other Income (Expenses)

Other income (expenses) increased by $42,000, or 21% from the year ended December 31, 2019 to the year ended December 31, 2020. The increase was due primarily to interest expense on outstanding convertible notes, which increased $105,000 from the prior year ended December 31, 2019. The increase was partially offset by a $63,000 loss on conversion of convertible notes in July 2019.

Liquidity and Capital Resources

Sources of Liquidity

Since our formation through March 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 $1,290,000 in convertible notes to investors. During the three months ended March 31, 2021, we raised $1,010,000 through the issuance of convertible notes to investors. We had cash of $147,000 on hand as of March 31, 2021.

Future Funding Requirements

We have incurred net losses since our inception. For the three months ended March 31, 2021, we had a net loss of $1.0 million, and we expect to incur substantial additional losses in future periods. As of March 31, 2021, we had an accumulated deficit of $6.9 million.

We expect to continue incurring losses for the foreseeable future and are required to raise additional capital 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 private 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. We believe that we will need funding by the end of the second quarter of 2021 to continue operations, satisfy our obligations and fund the future expenditures that will be required to conduct the clinical and regulatory work to develop our product candidates. There is substantial doubt about our ability to continue as a going concern for one year after the date that these financial statements are available to be issued, which is not alleviated by our plans. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary from the outcome of this uncertainty.

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 Unicycive's drug development program. The initial amended term of the Service Agreement expired on December 31, 2020, and the agreement shall automatically renew 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 March 31, 2021, and December 31, 2020, respectively, $10,000 was prepaid to and $9,000 was payable to Globavir for service fees. Service fee expenses were $30,000 and $30,000 for the three months ended March 31, 2021 and 2020, respectively, and were recorded as expense in general and administrative expenses in the statements of operations.

Convertible Notes

In January through March 2021, we issued convertible notes (the "2021 Notes") in the aggregate principal amount of $1,010,000. The 2021 Notes bear interest at a rate of 12% per annum, payable at maturity, and mature between January and March, 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 are accreting the carrying amount of the 2021 Notes to the settlement amount through maturity. As of March 31, 2021, unpaid and accrued interest of $17,000 as well as debt discount accretion expense of approximately $60,000 is included with the Convertible notes on the balance sheet.

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

We accounted for the 2020 Notes as stock-settled debt and we are accreting the carrying amount of the 2020 Notes to the settlement amount through maturity. As of December 31, 2020, unpaid and accrued interest of $53,000 as well as debt discount accretion expense of approximately $186,000 was included with the convertible notes on the balance sheet As of March 31, 2021, unpaid and accrued interest of $91,000 as well as debt discount accretion expense of approximately $323,000 is included with the convertible notes on the balance sheet.

In 2017 and 2018, we raised $550,000 from the issuance of twelve convertible promissory notes (the "2018 Notes"). The 2018 Notes bear interest at 10% per annum which was payable at maturity. The 2018 Notes' principal and interest were due and payable on written demand by the majority of the 2018 Note holders on the two-year anniversary of the first 2018 Note issued. The first 2018 Note was issued on October 5, 2017 and, accordingly, all 2018 Notes would have matured on October 5, 2019. In the event we consummated an equity financing with an aggregate sales price of not less than $500,000, then the aggregate outstanding principal and unpaid interest would automatically convert into shares of common stock. The per share price of the conversion would be equal to 75% of the price per share paid by the cash purchasers of the common stock sold in the financing.

We accounted for the 2018 Notes as stock-settled debt and accreted the carrying amount of the 2018 Notes to the settlement amount through maturity. On July 31, 2019, all 2018 Notes principal and accrued interest were converted into 1,159,065 shares of common stock upon the consummation of a 2019 equity financing in excess of $500,000. We recorded, as part of the conversion of the debt, a loss on conversion of $63,000 included in other expenses.

Interest expense was $252,000 and $2,000 for the three months ended March 31, 2021 and 2020, respectively. Accrued interest of $108,000 was included with the principal amount on the balance sheet within convertible notes as of March 31, 2021.

Interest expense was $244,000 and $139,000 for the years ended December 31, 2020 and 2019, respectively. Accrued interest of $53,000 was included with the principal amount on the balance sheet within convertible notes as of December 31, 2020.

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,		Three Months Ended March 31,	
	2019	2020	2020	2021
			(unaudited)	(unaudited)
Net cash (used in) provided by:				
Operating activities	$ (1,176)	$ (1,459)	$ (73)	$ (673)
Financing activities	1,166	1,444	60	820
Net (decrease) increase in cash	$ (10)	$ (15)	$ (13)	$ 147

Cash Flows from Operating Activities

Net cash used in operating activities was $1.5 million for the year ended December 31, 2020. Cash used in operating activities was primarily due to the use of funds in our operations for labor costs, accounting services, and consulting services to develop drug candidates, resulting in a net loss of $2.3 million, as well as the deferral of the chief executive officer compensation of $0.4 million.

Net cash used in operating activities was $1.2 million for the year ended December 31, 2019. Cash used in operating activities resulted from a net loss of $2.2 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 $0.3 million and an increase in accounts payable of $0.3 million.

Net cash used in operating activities was $0.7 million for the three months ended March 31, 2021. Cash used in operating activities was primarily due to the use of funds in our operations for labor costs, accounting services, and consulting services to develop drug candidates, resulting in a net loss of $1.0 million.

Net cash used in operating activities was $0.1 million for the three months ended March 31, 2020. Cash used in operating activities resulted from a net loss of $0.3 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 $0.1 million and an increase in accounts payable of $0.1 million.

Cash Flows from Financing Activities

Net cash provided by financing activities was $1.4 million for the year ended December 31, 2020 and was primarily related to the issuance of convertible notes to investors for $1.3 million.

Net cash provided by financing activities was $1.2 million for the year ended December 31, 2019 from the issuance of common stock to investors.

Net cash provided by financing activities was $0.8 million for the three months ended March 31, 2021 and was primarily related to the issuance of convertible notes to investors for $1.0 million as well as the receipt of $0.1 million in proceeds from the exercise of options. Net repayments on loans from our chief executive officer offset the cash inflows by $0.3 million.

Net cash provided by financing activities was $0.1 million for the three months ended March 31, 2020 from the issuance of common stock to investors.

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, stock-based compensation and common stock valuations. There have been no material changes to our critical accounting policies and estimates during the three months ended March 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. 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

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

In order to determine the fair value, 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.

Internal Controls and Procedures

In connection with the preparation of our financial statements, 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. The material weaknesses that we identified related to our finance department not having adequate staff to process, in a timely manner, complex, non-routine transactions, as well as not having adequate resources to perform such activities with duties properly segregated between processing and review. Furthermore, our policies, particularly related to approving related party transactions, have not been documented.

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 weaknesses 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.

Management is taking steps to remediate the material weaknesses in our internal control over financial reporting, including the identification of gaps in our skill set and expertise of the staff required to meet the financial reporting requirements of a public company. To address the issues, we have hired a financial consultant and plan to hire additional senior accounting personnel upon completion of this offering.

We will be required, pursuant to Section 404(a) of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control once we become a public company. This assessment will need to include disclosure of any material weaknesses identified by management over our internal control over financial reporting. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act until we are no longer an emerging growth company and a smaller reporting company.

We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We may not be able to complete our evaluation, testing or any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to conclude that our internal controls are designed and operating effectively.

JOBS Act Accounting Election

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

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

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of exemptions, including, without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. 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 this offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Recent Accounting Pronouncements

See the section titled "Summary of Significant Accounting Policies—Recent Accounting Pronouncements" in Note 2 to our financial statements included elsewhere in this prospectus for additional information.

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.

BUSINESS

Overview

We are a biotechnology company dedicated to developing treatments for unmet medical conditions. Currently, two of our programs are focused on kidney disease that have the potential to offer medical benefit. As we grow our company and build our team, we intend to be focused on identifying medical conditions within and outside kidney disease. Our current development programs are focused on the development of two novel therapies: UNI 218, or Renazorb, for treatment of hyperphosphatemia in patients with chronic kidney disease, and UNI 494, for treatment of acute kidney injury (AKI).

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

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

Our Strategy

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 past successful track record gives us an advantage in identifying and bringing these assets into the Company at an attractive price with limited upfront cost.

Key elements of our strategy are to:

- Develop and commercialize Renazorb;
- Develop UNI 494 and other licensed products and advance them at least to the stage of clinical proof-of-concept; and
- Build a core in-house team of experts that can create long-term value for our investors and for patients.

Recent Developments

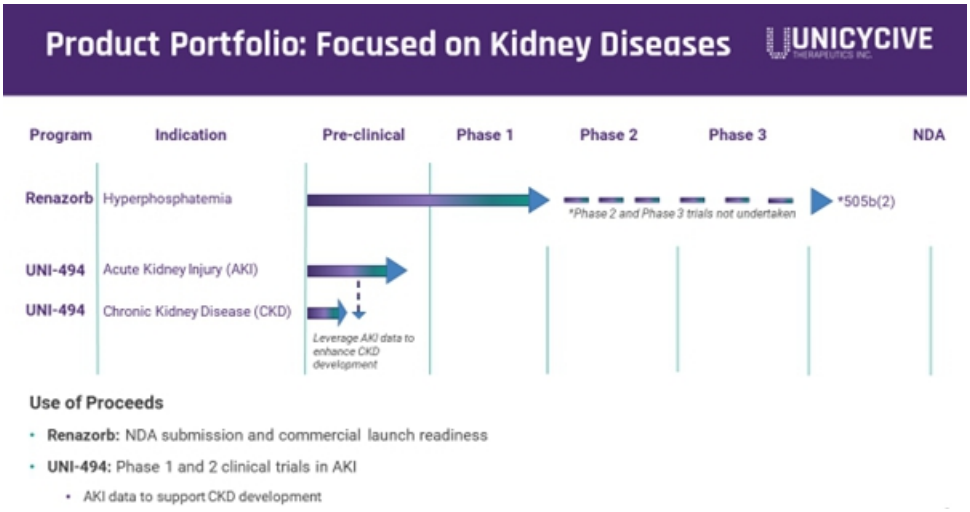
Ascent Master Services Agreement

On February 8, 2021, we 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 are expected to be completed by December 31, 2021.

Product Candidates

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 A. 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) in the US are estimated to 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.

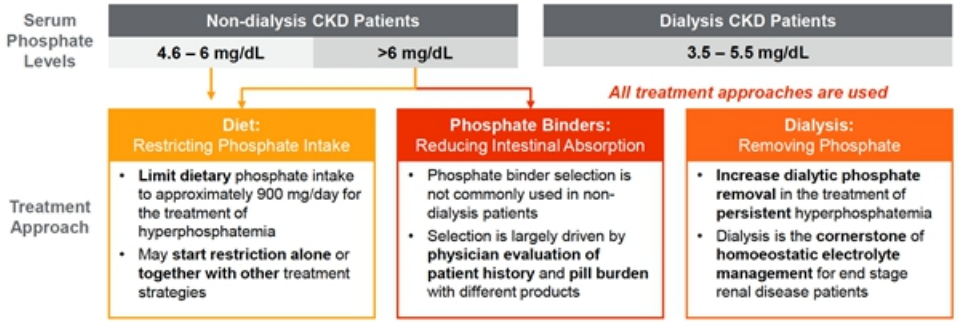


Figure 1: KDIGO guidelines recommend 3 main strategies

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.

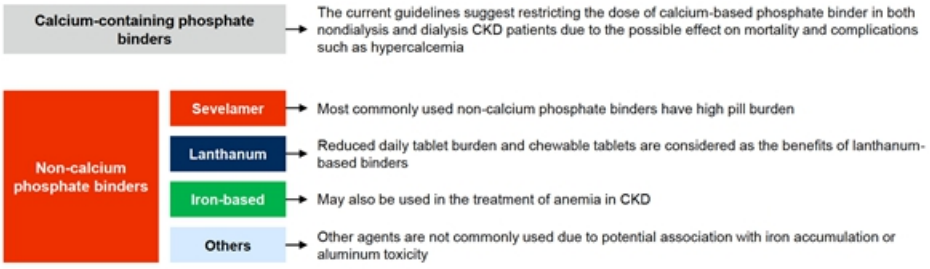


Figure 2: Phosphate Binders

This means that physicians prescribe their medication of choice, usually based on clinical and patient factors. In non-dialysis CKD patients, 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 Branded Products
Calcium carbonate	Forms insoluble phosphate complexes in the gut	Chewable tablets	Moderately effective, relatively inexpensive	Hypercalcaemia, large doses required to be effective, possible vascular calcification, unpalatable	Caltrate, Tums Regular Strength, Oyster Shell Calcium 500, Os-Cal
Sevelamer hydrochloride	An anion exchange resin	Tablets	Calcium-free, lipid-lowering effect	Lower phosphate binding capacity, expensive, high pill burden, gastrointestinal 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, gastrointestinal 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, gastrointestinal adverse effects	Velphoro
Ferric citrate	Forms insoluble phosphate complexes in the gut	Tablets	Also serves as treatment for anemia in CKD	Expensive, high pill burden, gastrointestinal adverse effects and cough	Auryxia
Aluminum hydroxide	Forms insoluble phosphate complexes in the gut	Tablets	Inexpensive, calcium-free, binds phosphate at wide range of pH	No safe dose established, significant adverse effects, requires regular monitoring of serum aluminium	AlternaGEL, Amphojel, 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 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 burden, (ii) improvement of palatability (taste), 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 low solubility, 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 patients with ESRD or in those with early stages of CKD. 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. 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.

Renazorb Purchase Agreement

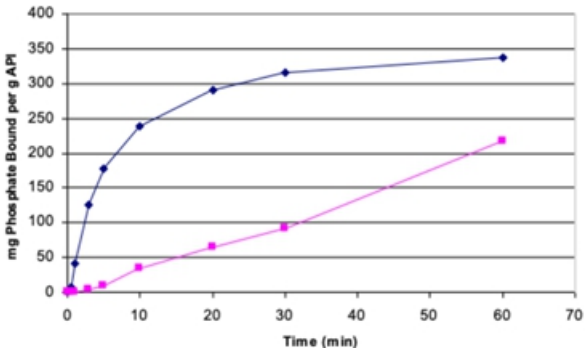
On September 20, 2018, we entered into an Assignment and Asset Purchase Agreement (the "Renazorb Purchase Agreement") with Spectrum Pharmaceuticals, Inc. ("Spectrum"), pursuant to which we purchased certain assets from Spectrum, including Spectrum's right, title, interest in and intellectual property 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 1,348,750 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 an in vitro test, Renazorb exhibited more phosphate binding kinetics than lanthanum carbonates (such as Fosrenol) (see figure below). In addition, it has a lower water solubility at various pH values than the corresponding lanthanum carbonates and also produces less carbon dioxide than Fosrenol when binding with phosphate.



Source: Company Data
Blue line = Renazorb (phosphate binding capacity 338 mg/g)
Pink line = Fosrenol (phosphate binding capacity 217 mg/g)

Figure 3: Renazorb binding characteristics as compared with those of Fosrenol in in vitro testing

Animal studies to evaluate the potential efficacy of Renazorb versus lanthanum carbonate (Fosrenol) and sevelamer hydrochloride in rats and dogs demonstrated significant lowering of phosphate levels in both urine and serum. Low levels of lanthanum were observed in serum which were comparable for Renazorb and Fosrenol.

The chemical design of Renazorb allows for smaller tablet size and pill burden versus currently available alternatives of phosphate binders, 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. 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 hyperphosphatemia in ESRD and is intended to be administered as a tablet that will be swallowed whole at mealtimes. CKD patients typically have co-morbidities, which often requires 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 pill burden and lack of unpleasant taste 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

According to a study conducted by Syneos Health for the Company, based on the market data, the total hyperphosphatemia market was estimated to be approximately $1.05 billion in 2018.

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 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

We are pursuing a 505(b)(2) regulatory pathway for the potential US approval of Renazorb. With this strategy, we believe we would be able to leverage existing preclinical and clinical data for an existing lanthanum-based product (Fosrenol) to reduce the overall scope of the required clinical development program. We have met with and discussed this strategy with the U.S. Food and Drug Administration, or FDA, and we believe that pursuit of such a strategy will require the following studies for Renazorb:

- in vitro comparability of phosphate binding versus lanthanum carbonate
- 6-month oral toxicity study in one animal species
- Standard information on manufacturability and commercial supply of product

Activities in support of each of the requirements recommended by FDA are underway, and we believe that we can complete these activities by the first half of 2022. It is our intention to hold additional discussions with FDA during the second half of 2021, including a Pre-NDA meeting, to confirm their concurrence with our dataset and NDA submission strategy.

During our previous interaction, the FDA indicated that some amount of clinical experience will be needed to assess safety and tolerability of Renazorb, a request which we believe is satisfied by our existing Phase 1 clinical safety and tolerability study. We believe that those data along with the planned phosphate binding comparability study will enable a 505(b)(2) NDA filing approach for Renazorb. Following our next FDA interaction in 2021, in the event that FDA requests additional clinical data, we would intend to fulfill this request with a single open-label 8-week safety, tolerability, and efficacy dose-ranging study of Renazorb in hyperphosphatemic patients on hemodialysis, which we believe could be completed by the second half of 2022.

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, Acute Kidney Disease (AKD) 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).

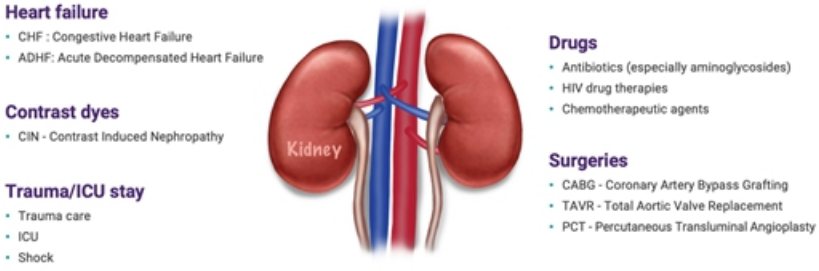


Figure 6: Adapted from Nature Review-Nephrology; Chawla LS et al. 2017

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 Anaesthesiology 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 preexisting 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. 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 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 renal replacement therapy, renal transplant and radical surgery 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 and developed, UNI 494 (a patented prodrug 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.

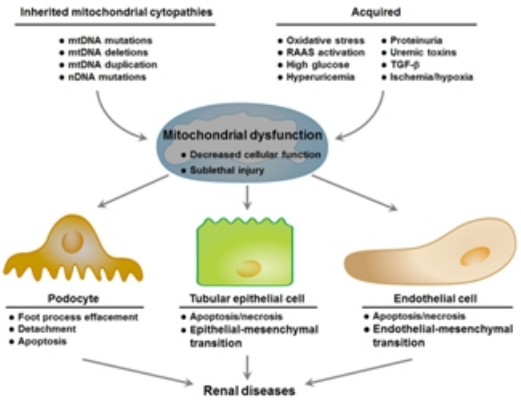
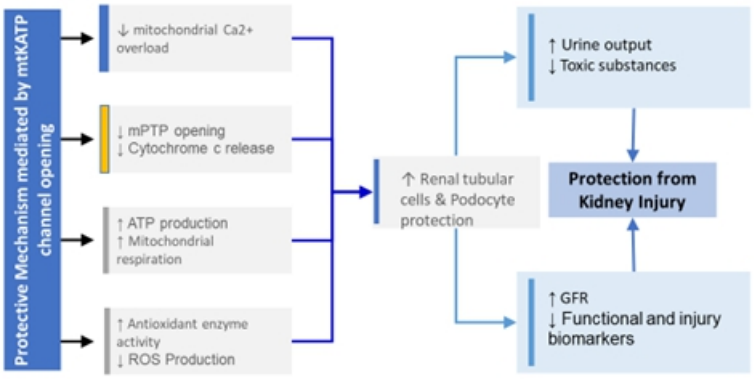


Figure 7: Che R, 2014: Mitochondria Dysfunction

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 and 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 in table 5 below. 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

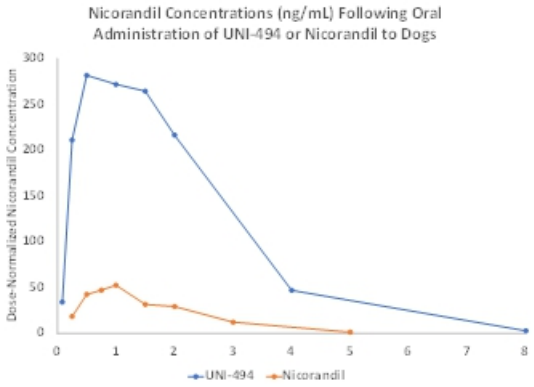
Despite these promising results, development of nicorandil for use in acute kidney injury has not been successfully pursued to date. Nicorandil possesses at least two features that may limit its use in this clinical setting. First, nicorandil has a short half-life in humans of approximately 1 hour, which 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 physochemical characterization and preliminary animal pharmacokinetic studies. Sphaera conceived of and performed initial characterization of various potential pro-drug linkers, including the initial patent application, and performed some initial physochemical 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 the drug and discussions with key opinion leaders (KOLs), we believe that the AKI subsets where UNI 494 can be most active is in patients who have either prior cardiac dysfunction or patients with liver dysfunction. 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 and patients who have been in intensive care units. These 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, potentially using a 505(b)(2) pathway. However, there is no guarantee that the FDA will approve a request to use a 505(b)(2) pathway and if not, we plan to pursue a standard clinical development and regulatory approval pathway for UNI 494.

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.

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.

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 Regulation and Approval Process

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 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.

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 diseae 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.

Employees and Labor Relations

As of the date of this prospectus, we have one full time employee and seven (7) consultants. We have no collective bargaining agreements with our employee, and none are represented by labor unions. We consider our current relations with our employee to be good.

Facilities

Our principal address is 5150 El Camino Real, Suite A-32, 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.

Legal Proceedings

From time to time we may be involved in claims that arise during the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we do not currently have any pending litigation to which we are a party or to which our property is subject that we believe to be material. Regardless of the outcome, litigation can be costly and time consuming, and it can divert management's attention from important business matters and initiatives, negatively impacting our overall operations.

MANAGEMENT

Directors and Executive Officers

The following table sets forth the name, age and position of each of our executive officers, key employee, consultants and directors as of the date of this prospectus.

Name	Age	Position
Shalabh Gupta, M.D.	48	Chief Executive Officer, President and Chairman of the Board of Directors
Pramod Gupta, M.D.	60	Executive Vice President, Pharmaceutical and Business Operations
John Townsend	59	Chief Financial Officer
John Ryan, M.D., Ph.D.	77	Director
Sandeep Laumas, M.D.	52	Director
Brigitte Schiller, M.D. (1)	61	Director Nominee

(1) The board of directors intends to appoint Dr. Schiller as a director upon the completion of this offering.

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, M.D. Dr. Gupta has been our Executive Vice President, Pharmaceutical and Business Operations since September 2020 in a consulting role. 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 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 is a nominee for appointment as a director, and such appointment will be effective upon completion of this offering. 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.

Director Independence

Prior to the consummation of this offering, 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 have affirmatively determined that Dr. Laumas, Dr. Ryan, and Dr. Schiller will be "independent directors," as defined under the Nasdaq rules.

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. Upon the completion of this offering we will have a standing audit committee, compensation committee and nominating and corporate governance 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.

Upon the consummation of this offering, our audit committee will consist of Dr. Laumas, Dr. Ryan, and Dr. Schiller, with Dr. Laumas serving as chair. Our board of directors has affirmatively determined that each will meet 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 will qualify as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K. Our board of directors will adopt a written charter for the audit committee, which will be available on our principal corporate website at *http://www.unicycive.com* concurrently with the consummation of this offering.

Compensation Committee

Our compensation committee will be responsible for, among other things:

- reviewing and recommending the compensation arrangements for management, including the compensation for our president and 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.

Upon the consummation of this offering, our compensation committee will consist 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 will adopt a written charter for the compensation committee, which will be available on our principal corporate website at *http://www.unicycive.com* concurrently with the consummation of this offering.

Nominating and Governance Committee

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

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

Upon the consummation of this offering, our nominating and corporate governance committee will consist 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 will adopt a written charter for the nominating and governance committee, which will be available on our principal corporate website at *http://www.unicycive.com* concurrently with the consummation of this offering.

Code of Business Conduct and Ethics

Prior to the completion of this offering, we will adopt 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 will be posted on our website, *www.unicycive.com*. In addition, we intend to post on our website all disclosures that are required by law or the Nasdaq rules concerning any amendments to, or waivers from, any provision of the code.

Limitations on Liability and Indemnification Matters

Our Amended and Restated Certificate of Incorporation, to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our Amended and Restated Certificate of Incorporation, to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, will provide that we are authorized to indemnify our directors and officers to the fullest extent permitted by Delaware law. Our Amended and Restated Bylaws, to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, will provide that we are required to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. Our Amended and Restated Bylaws will also provide that, upon satisfaction of certain conditions, we may advance expenses incurred by a director or executive officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. Our Amended and Restated Bylaws will also provide our board of directors with discretion to indemnify our other officers and employees when determined appropriate by our board of directors. We expect to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses, including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain and intend to continue to maintain obtain customary directors' and officers' liability insurance upon consummation of this offering.

The limitation of liability and indemnification provisions in our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws to be in effect immediately prior to the effectiveness of the registration statement of which this prospectus forms a part may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

EXECUTIVE AND DIRECTOR COMPENSATION

Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to each of our named executive officers for each of the years ended December 31, 2020 and 2019.

Name and Principal Position	Year	Salary[1] ($)	Bonus ($)	Stock awards ($)	Option Awards [2] ($)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Shalabh Gupta, M.D.,	2020	495,000	148,500	-	-	-	-	-	643,500
Chief Executive Officer	2019	350,000	50,000	-	-	-	-	-	400,000
Pramod Gupta, M.D.,	2020	-	-	-	212,250	-	-	60,000	272,250
Executive VP Pharmaceutical and Business Operation	2019	-	-	-	250,775	-	-	15,000	265,775

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

(2) The amounts reported in this column represent 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.

Outstanding Equity Awards at December 31, 2020

The following table provides information regarding awards held by each of our named executive officers that were outstanding as of December 31, 2020. There were no other equity awards held by our named executive officers outstanding as of December 31, 2020.

Name	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*	816,667	583,333	0.003	07/25/2023
Pramod Gupta, M.D., *Executive Vice President, Pharmaceutical and Business Operations*	65,624	509,376	0.76	10/01/2029 – 04/06/2030

Non-Employee Director Compensation

We did not compensate our non-employee directors for their service during the fiscal year ended December 31, 2020.

Employment Agreements

We have entered into the following employment agreements with our Named Executive Officers:

Shalabh Gupta Employment Agreement

On May 18, 2021, we entered into an employment agreement with Dr. Gupta, to be effective upon the closing of this offering, 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, as soon as reasonably practicable after the date of an initial public offering of the Company, he will receive a one-time equity grant of 500,000 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 we entered into an employment agreement with Mr. Gupta, pursuant to which Mr. Gupta serves as our Executive Vice President, Pharmaceutical and Business Operations. On April 28, 2021, we entered into an amendment to the employment agreement with Mr. Gupta to clarify that the agreement was to be effective upon the closing of this offering. 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, as soon as reasonably practicable after the date of an initial public offering of the Company, he will receive a one-time equity grant of 150,000 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.

Bonus Arrangements

Our practice with respect to annual incentive compensation has historically been to provide an opportunity to earn bonus awards based on the achievement of company performance measures. See "Employment Agreements" above for a description of bonuses that may be payable to certain of our named executive officers pursuant to their employment agreements.

2018 Equity Incentive Plan

In 2018, we adopted the 2018 Equity Incentive Plan (the "2018 Plan") in order to attract and retain the best available personnel for positions of substantial responsibility, to provide additional incentives to our employees, directors and consultants, and to promote the success of our business. We have reserved 2,000,000 shares of common stock for issuance under the 2018 Plan. The 2018 Plan provides for the issuance of stock options, stock appreciation rights ("SARs"), restricted stock and restricted stock units ("RSUs"). The 2018 Plan will terminate upon the expiration of a ten (10) year term, and awards issued thereunder shall expire as provided in the award agreement with respect thereto.

2019 Stock Option Plan

In 2019, we adopted the 2019 Stock Option Plan (the "2019 Plan") in order to attract and retain the best available personnel for positions of substantial responsibility, to provide additional incentives to our employees, directors and consultants, and to promote the success of our business. We originally reserved 1,500,000 shares of common stock for issuance under the 2019 Plan, and on February 17, 2021, our board of directors approved an increase of authorized shares in the 2019 Plan from 1,500,000 to 7,600,000 shares of common stock. The 2019 Plan provides for the issuance of incentive stock options and non-statutory stock options. The 2019 Plan will terminate upon the expiration of a ten (10) year term, and awards issued thereunder shall expire as provided in the award agreement with respect thereto.

2021 Omnibus Equity Incentive Plan

In connection with this offering, and as approved by our Board of Directors, we will adopt 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.

Types of Awards. The 2021 Plan provides for the issuance of incentive stock options, non-statutory stock options, stock appreciation rights ("SARs"), restricted stock, restricted stock units ("RSUs"), and other stock-based awards.

Administration. The 2021 Plan will be administered by our board of directors, or if our board of directors does not administer the 2021 Plan, a committee or subcommittee of our board of directors that complies with the applicable requirements of Section 16 of the Exchange Act and any other applicable legal or stock exchange listing requirements (each of our board of directors or such committee or subcommittee, the "plan administrator"). The plan administrator may interpret the 2021 Plan and may prescribe, amend and rescind rules and make all other determinations necessary or desirable for the administration of the 2021 Plan, provided that, subject to the equitable adjustment provisions described below, the plan administrator will not have the authority to reprice or cancel and re-grant any award at a lower exercise, base or purchase price or cancel any award with an exercise, base or purchase price in exchange for cash, property or other awards without first obtaining the approval of our stockholders.

The 2021 Plan permits the plan administrator to select the eligible recipients who will receive awards, to determine the terms and conditions of those awards, including but not limited to the exercise price or other purchase price of an award, the number of shares of common stock or cash or other property subject to an award, the term of an award and the vesting schedule applicable to an award, and to amend the terms and conditions of outstanding awards.

Restricted Stock and Restricted Stock Units. Restricted stock and RSUs may be granted under the 2021 Plan. The plan administrator will determine the purchase price, vesting schedule and performance goals, if any, and any other conditions that apply to a grant of restricted stock and RSUs. If the restrictions, performance goals or other conditions determined by the plan administrator are not satisfied, the restricted stock and RSUs will be forfeited. Subject to the provisions of the 2021 Plan and the applicable award agreement, the plan administrator has the sole discretion to provide for the lapse of restrictions in installments.

Unless the applicable award agreement provides otherwise, participants with restricted stock will generally have all of the rights of a stockholder; provided that dividends will only be paid if and when the underlying restricted stock vests. RSUs will not be entitled to dividends prior to vesting, but may be entitled to receive dividend equivalents if the award agreement provides for them. The rights of participants granted restricted stock or RSUs upon the termination of employment or service to us will be set forth in the award agreement.

Options. Incentive stock options and non-statutory stock options may be granted under the 2021 Plan. An "incentive stock option" means an option intended to qualify for tax treatment applicable to incentive stock options under Section 422 of the Internal Revenue Code. A "non-statutory stock option" is an option that is not subject to statutory requirements and limitations required for certain tax advantages that are allowed under specific provisions of the Internal Revenue Code. A non-statutory stock option under the 2021 Plan is referred to for federal income tax purposes as a "non-qualified" stock option. Each option granted under the 2021 Plan will be designated as a non-qualified stock option or an incentive stock option. At the discretion of the administrator, incentive stock options may be granted only to our employees, employees of our "parent corporation" (as such term is defined in Section 424(e) of the Code) or employees of our subsidiaries.

The exercise period of an option may not exceed ten years from the date of grant and the exercise price may not be less than 100% of the fair market value of a share of common stock on the date the option is granted (110% of fair market value in the case of incentive stock options granted to ten percent stockholders). The exercise price for shares of common stock subject to an option may be paid in cash, or as determined by the administrator in its sole discretion, (i) through any cashless exercise procedure approved by the administrator (including the withholding of shares of common stock otherwise issuable upon exercise), (ii) by tendering unrestricted shares of common stock owned by the participant, (iii) with any other form of consideration approved by the administrator and permitted by applicable law or (iv) by any combination of these methods. The option holder will have no rights to dividends or distributions or other rights of a stockholder with respect to the shares of common stock subject to an option until the option holder has given written notice of exercise and paid the exercise price and applicable withholding taxes.

In the event of an participant's termination of employment or service, the participant may exercise his or her option (to the extent vested as of such date of termination) for such period of time as specified in his or her option agreement.

Stock Appreciation Rights.

SARs may be granted either alone (a "free-standing SAR") or in conjunction with all or part of any option granted under the 2021 Plan (a "tandem SAR"). A free-standing SAR will entitle its holder to receive, at the time of exercise, an amount per share up to the excess of the fair market value (at the date of exercise) of a share of common stock over the base price of the free-standing SAR (which shall be no less than 100% of the fair market value of the related shares of common stock on the date of grant) multiplied by the number of shares in respect of which the SAR is being exercised. A tandem SAR will entitle its holder to receive, at the time of exercise of the SAR and surrender of the applicable portion of the related option, an amount per share up to the excess of the fair market value (at the date of exercise) of a share of common stock over the exercise price of the related option multiplied by the number of shares in respect of which the SAR is being exercised. The exercise period of a free-standing SAR may not exceed ten years from the date of grant. The exercise period of a tandem SAR will also expire upon the expiration of its related option.

The holder of a SAR will have no rights to dividends or any other rights of a stockholder with respect to the shares of Common Stock subject to the SAR until the holder has given written notice of exercise and paid the exercise price and applicable withholding taxes.

In the event of an participant's termination of employment or service, the holder of a SAR may exercise his or her SAR (to the extent vested as of such date of termination) for such period of time as specified in his or her SAR agreement.

Other Stock-Based Awards. The administrator may grant other stock-based awards under the 2021 Plan, valued in whole or in part by reference to, or otherwise based on, shares of common stock. The administrator will determine the terms and conditions of these awards, including the number of shares of common stock to be granted pursuant to each award, the manner in which the award will be settled, and the conditions to the vesting and payment of the award (including the achievement of performance goals). The rights of participants granted other stock-based awards upon the termination of employment or service to us will be set forth in the applicable award agreement. In the event that a bonus is granted in the form of shares of common stock, the shares of common stock constituting such bonus shall, as determined by the administrator, be evidenced in uncertificated form or by a book entry record or a certificate issued in the name of the participant to whom such grant was made and delivered to such participant as soon as practicable after the date on which such bonus is payable. Any dividend or dividend equivalent award issued hereunder shall be subject to the same restrictions, conditions and risks of forfeiture as apply to the underlying award.

Equitable Adjustment and Treatment of Outstanding Awards Upon a Change in Control

Equitable Adjustments. In the event of a merger, consolidation, reclassification, recapitalization, spin-off, spin-out, repurchase, reorganization, special or extraordinary dividend or other extraordinary distribution (whether in the form of common shares, cash or other property), combination, exchange of shares, or other change in corporate structure affecting our common stock, an equitable substitution or proportionate adjustment shall be made in (i) the aggregate number and kind of securities reserved for issuance under the 2021 Plan, (ii) the kind and number of securities subject to, and the exercise price of, any outstanding options and SARs granted under the 2021 Plan, (iii) the kind, number and purchase price of shares of common stock, or the amount of cash or amount or type of property, subject to outstanding restricted stock, RSUs and other stock-based awards granted under the 2021 Plan and (iv) the terms and conditions of any outstanding awards (including any applicable performance targets). Equitable substitutions or adjustments other than those listed above may also be made as determined by the plan administrator. In addition, the plan administrator may terminate all outstanding awards for the payment of cash or in-kind consideration having an aggregate fair market value equal to the excess of the fair market value of the shares of common stock, cash or other property covered by such awards over the aggregate exercise price, if any, of such awards, but if the exercise price of any outstanding award is equal to or greater than the fair market value of the shares of common stock, cash or other property covered by such award, the plan administrator may cancel the award without the payment of any consideration to the participant. With respect to awards subject to foreign laws, adjustments will be made in compliance with applicable requirements. Except to the extent determined by the plan administrator, adjustments to incentive stock options will be made only to the extent not constituting a "modification" within the meaning of Section 424(h)(3) of the Code.

Change in Control. The 2021 Plan provides that, unless otherwise determined by the plan administrator and evidenced in an award agreement, if a "change in control" (as defined below) occurs and a participant is employed by us or any of our affiliates immediately prior to the consummation of the change in control, then the plan administrator, in its sole and absolute discretion, may (i) provide that any unvested or unexercisable portion of an award carrying a right to exercise will become fully vested and exercisable; and (ii) cause the restrictions, deferral limitations, payment conditions and forfeiture conditions applicable to any award granted under the 2021 Plan to lapse, and the awards will be deemed fully vested and any performance conditions imposed with respect to such awards will be deemed to be fully achieved at target performance levels. The administrator shall have discretion in connection with such change in control to provide that all outstanding and unexercised options and SARs shall expire upon the consummation of such change in control.

For purposes of the 2021 Plan, a "change in control" means, in summary, the first to occur of the following events: (i) a person or entity becomes the beneficial owner of more than 50% of our voting power; (ii) an unapproved change in the majority membership of our board of directors; (iii) a merger or consolidation of us or any of our subsidiaries, other than (A) a merger or consolidation that results in our voting securities continuing to represent 50% or more of the combined voting power of the surviving entity or its parent and our board of directors immediately prior to the merger or consolidation continuing to represent at least a majority of the board of directors of the surviving entity or its parent or (B) a merger or consolidation effected to implement a recapitalization in which no person is or becomes the beneficial owner of our voting securities representing more than 50% of our combined voting power; or (iv) stockholder approval of a plan of our complete liquidation or dissolution or the consummation of an agreement for the sale or disposition of substantially all of our assets, other than (A) a sale or disposition to an entity, more than 50% of the combined voting power of which is owned by our stockholders in substantially the same proportions as their ownership of us immediately prior to such sale or (B) a sale or disposition to an entity controlled by our board of directors. However, a change in control will not be deemed to have occurred as a result of any transaction or series of integrated transactions following which our stockholders, immediately prior thereto, hold immediately afterward the same proportionate equity interests in the entity that owns all or substantially all of our assets.

Tax Withholding

Each participant will be required to make arrangements satisfactory to the plan administrator regarding payment of up to the maximum statutory tax rates in the participant's applicable jurisdiction with respect to any award granted under the 2021 Plan, as determined by us. We have the right, to the extent permitted by applicable law, to deduct any such taxes from any payment of any kind otherwise due to the participant. With the approval of the plan administrator, the participant may satisfy the foregoing requirement by either electing to have us withhold from delivery of shares of common stock, cash or other property, as applicable, or by delivering already owned unrestricted shares of common stock, in each case, having a value not exceeding the applicable taxes to be withheld and applied to the tax obligations. We may also use any other method of obtaining the necessary payment or proceeds, as permitted by applicable law, to satisfy our withholding obligation with respect to any award.

Amendment and Termination of the 2021 Plan

The 2021 Plan provides our board of directors with authority to amend, alter or terminate the 2021 Plan, but no such action impair the rights of any participant with respect to outstanding awards without the participant's consent. The plan administrator may amend an award, prospectively or retroactively, but no such amendment may materially impair the rights of any participant without the participant's consent. Stockholder approval of any such action will be obtained if required to comply with applicable law. The 2021 Plan will terminate on the tenth anniversary of the Effective Date (although awards granted before that time will remain outstanding in accordance with their terms).

Clawback

If we are required to prepare a financial restatement due to the material non-compliance with any financial reporting requirement, then the plan administrator may require any Section 16 officer to repay or forfeit to us that part of the cash or equity incentive compensation received by that Section 16 officer during the preceding three years that the plan administrator determines was in excess of the amount that such Section 16 officer would have received had such cash or equity incentive compensation been calculated based on the financial results reported in the restated financial statement. The plan administrator may take into account any factors it deems reasonable in determining whether to seek recoupment of previously paid cash or equity incentive compensation and how much of such compensation to recoup from each Section 16 officer (which need not be the same amount or proportion for each Section 16 officer). The amount and form of the incentive compensation to be recouped shall be determined by the administrator in its sole and absolute discretion.

Other Benefits

We do not currently offer customary benefits for our employees, Upon the completion of this offering, we intend to establish broad-based and comprehensive employee benefit programs, including medical, dental, vision, life and disability insurance. We do not sponsor or maintain any deferred compensation or supplemental retirement plans.

Non-Employee Director Compensation

We did not compensate our non-employee directors for their service during the fiscal year ended December 31, 2020.

In connection with the completion of this offering, we plan to adopt a non-employee director compensation policy pursuant to which we will compensate non-employee directors for their service to the Company. Directors who are also employees do not receive cash or equity compensation for service on our Board of Directors in addition to compensation payable for their service as employees of the Company.

Under our non-employee director compensation policy, we provide cash compensation in the form of an annual retainer of $40,000 for each non-employee director. We also pay an additional annual retainer of $15,000 to the chair of our audit committee, $7,500 to other non-employee directors who serve on our audit committee, $10,000 to the chair of our compensation committee, $5,000 to other non-employee directors who serve on our compensation committee, $8,000 to the chair of our nominating and corporate governance committee and $4,000 to other non-employee directors who serve on our nominating and corporate governance committee.

Also under our non-employee director compensation policy, upon joining our Board of Directors, each new non-employee director shall receive a grant of stock options with respect to shares of our common stock valued at $50,000. Such options will have an exercise price equal to the fair market value of our common stock on the date of grant. In addition, each new non-employee director shall receive an additional grant of restricted stock units valued at $50,000. Further, on an annual basis, each non-employee director shall also be entitled to receive an additional equity award valued at $50,000.

The value of each equity grant issued under our non-employee director compensation policy will be convertible into shares of our common stock based on the fair market value of such shares on the date of grant, as determined under our 2021 Plan, with each option valued at one-third (1/3) of the value of a share of our common stock.

The initial options and restricted stock units granted to non-employee directors, as well as the annual equity awards granted to non-employee directors, will vest in full upon the one-year anniversary of the date of grant, subject to the director's continuing service on our board of directors on those dates. These equity awards will be granted under our 2021 Plan.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

The following includes a summary of transactions during our fiscal years ended December 31, 2020 and December 31, 2019 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 prospectus. 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.

On July 1, 2017, we entered into a Service Agreement with Globavir Biosciences, Inc. ("Globavir"), as amended on April 6, 2020, pursuant to which Globavir provides us (i) with access to and use of certain office space; (ii) administrative office services and equipment; (iii) access to and use of consulting services of Globavir's employees in connection with our drug development programs; and (iv) such other administrative and consulting services as are agreed upon by us and Globavir from time to time. 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. The Service Agreement shall continue until December 31, 2020 (the "Initial Term") unless earlier terminated pursuant to the terms thereof. Unless terminated, the Service Agreement shall automatically renew for successive one month periods after the termination of the Initial Term. As of December 31, 2020 and 2019, $9,000 and $108,000, respectively, is owed by us for such services. As of March 31, 2021, we prepaid $10,000 for such services. Our Chief Executive Officer is the Chief Executive Officer and principal stockholder of Globavir.

Related Person Transaction Policy

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. Upon consummation of this offering, we shall adopt a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. The policy will become effective immediately upon the execution of the underwriting agreement for this offering. 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 the average 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.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information regarding the beneficial ownership of our common stock as of May 19, 2021 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 May 19, 2021, 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 37,682,715 shares of common stock issued and outstanding as of May 19, 2021.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each director and executive officer listed is: c/o Unicycive Therapeutics, Inc., 5150 El Camino Real, Suite A-32, Los Altos, CA 94022.

Name of Beneficial Owner	Number of Shares Beneficially Owned Prior to Offering	Percentage of Common Stock Beneficially Owned	
		Before Offering	After Offering
Directors and Named Executive Officers:			
Shalabh Gupta, M.D.	24,856,911(1)	65.96%	%
John Ryan, M.D., Ph.D.	286,458(2)	*%	%
Sandeep Laumas, M.D.	491,458(3)	1.30%	%
Pramod Gupta, Ph.D.	214,060(4)	*%	%
All current named executive officers and directors as a group (5 persons)	25,848,887	**68.08%**	%

* less than 1%

(1) Includes an aggregate of (i) 24,798,578 shares of common stock held by Dr. Gupta and/or entities controlled by Dr. Gupta; and (ii) 58,333 shares of common stock that will vest within 60 days of May 19, 2021.

(2) Includes an aggregate of (i) 250,000 shares of common stock held by Dr. Ryan (ii) 34,375 shares of common stock underlying vested options to purchase shares of common stock; and (iii) 2,083 shares of common stock that will vest within 60 days of May 19, 2021.

(3) Includes an aggregate of (i) 455,000 shares of common stock held by Dr. Laumas and/or entities controlled by Dr. Laumas; (ii) 34,375 shares of common stock underlying vested options to purchase shares of common stock; and (iii) 2,083 shares of common stock that will vest within 60 days of May 19, 2021.

(4) Includes an aggregate of (i) 190,103 shares of common stock underlying vested options to purchase shares of common stock; and (ii) 23,957 shares of common stock that will vest within 60 days of May 19, 2021.

DESCRIPTION OF CAPITAL STOCK

General

Our authorized capital stock consists of 200,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share.

As of May 19, 2021, there were 37,682,715 shares of our common stock issued and outstanding held by 111 holders of record.

The following description of our capital stock and provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part is only a summary. You should also refer to our Amended and Restated Certificate of Incorporation, a copy of which is filed as an exhibit to the registration statement of which this prospectus is a part, and our Amended and Restated Bylaws, a copy of which is filed as an exhibit to the registration statement of which this prospectus is a part.

Reverse Stock Split

Upon filing, our Amended and Restated Certificate of Incorporation will effectuate a one-for- (1:) reverse stock split (the "Reverse Stock Split") of our common stock without any change to its par value. No fractional shares will be issued in connection with the Reverse Stock Split as all fractional shares will be rounded up to the next whole share.

Common Stock

We are authorized to issue up to a total of 200,000,000 shares of common stock, par value $0.001 per share. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of our stockholders. Holders of our common stock have no cumulative voting rights.

Further, holders of our common stock have no preemptive or conversion rights or other subscription rights. 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. 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. Each outstanding share of our common stock is, and all shares of common stock to be issued in this offering when they are paid for will be, fully paid and non-assessable.

The holders of a majority of the shares of our capital stock, represented in person or by proxy, are necessary to constitute a quorum for the transaction of business at any meeting. If a quorum is present, an action by stockholders entitled to vote on a matter is approved if the number of votes cast in favor of the action exceeds the number of votes cast in opposition to the action, with the exception of the election of directors, which requires a plurality of the votes cast.

Preferred Stock

Our board of directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the designations, powers, preferences, privileges, and relative participating, optional, or special rights as well as the qualifications, limitations, or restrictions of the preferred stock, including dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, any or all of which may be greater than the rights of the common stock. Our board of directors, without stockholder approval, will be able to issue convertible preferred stock with voting, conversion, or other rights that could adversely affect the voting power and other rights of the holders of common stock. Preferred stock could be issued quickly with terms calculated to delay or prevent a change of control or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock, and may adversely affect the voting and other rights of the holders of common stock. At present, we have no plans to issue any shares of preferred stock following this offering.

Options

Our 2018 Equity Incentive Plan provides for us to sell or issue shares of common stock or restricted shares of common stock, or to grant incentive stock options or nonqualified stock options, SARs and RSU awards for the purchase of shares of common stock to certain service providers. As of March 31, 2021, 75,000 shares of our common stock were reserved for future issuance under our 2018 Plan. For additional information regarding the terms of the 2018 Plan, see "Executive and Director Compensation—2018 Equity Incentive Plan."

Our 2019 Stock Option Plan provides for us to grant incentive stock options or nonqualified stock options for the purchase of shares of common stock to certain service providers. As of March 31, 2021, 5,577,000 shares of our common stock were reserved for future issuance under our 2019 Plan. For additional information regarding the terms of the 2019 Plan, see "Executive and Director Compensation—2019 Stock Option Plan."

In connection with this offering, and as approved by our Board of Directors, we will adopt 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. The 2021 Plan provides for the issuance of incentive stock options, non-statutory stock options, stock appreciation rights ("SARs"), restricted stock, restricted stock units ("RSUs"), and other stock-based awards.

Exclusive Forum

Our Amended and Restated Certificate of Incorporation, to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, 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 DGCL or our Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws to be effective upon completion of this offering, 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 or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our Amended and Restated Certificate of Incorporation, to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, 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 these provisions. 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 such provision, if applicable.

Anti-Takeover Provisions of Delaware Law, our Amended and Restated Certificate of Incorporation and our Amended and Restated Bylaws

Delaware Law

We are governed by the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly traded Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A business combination includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An interested stockholder is a person who, together with affiliates and associates, owns (or within three years, did own) 15% or more of the corporation's voting stock, subject to certain exceptions. The statute could have the effect of delaying, deferring or preventing a change in control of our Company.

Board of Directors Vacancies

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, each to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, authorize only our board of directors to fill vacant directorships. In addition, the number of directors constituting our board of directors may be set only by resolution of the majority of the incumbent directors.

Special Meeting of Stockholders

Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, each to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, further provide that special meetings of our stockholders may be called by a majority of the board of directors, the Chief Executive Officer, or the Chairman of the board of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our Amended and Restated Bylaws, to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, provide that stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders, must provide timely notice of their intent in writing. To be timely, a stockholder's notice must be delivered to the secretary at our principal executive offices not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event the date of the annual meeting is more than 30 days before or more than 60 days after such anniversary date, or if no annual meeting was held in the preceding year, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of the 90th day prior to such annual meeting or the 10th day following the day on which a public announcement of the date of such meeting is first made by us. These provisions may preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval and may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise. If we issue such shares without stockholder approval and in violation of limitations imposed by the Nasdaq Capital Market or any stock exchange on which our stock may then be trading, our stock could be delisted.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Philadelphia Stock Transfer, 2320 Haverford Rd, Suite 230, Ardmore, PA 19003.

Stock Market Listing

We have applied to have our shares of common stock listed for trading on the Nasdaq Capital Market under the symbol "UNCY." No assurance can be given that such listing will be approved.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, or the anticipation of these sales, could materially and adversely affect market prices prevailing from time to time, and could impair our ability to raise capital through sales of equity or equity-related securities.

Only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after completion of this offering due to contractual and legal restrictions on resale described below. Nevertheless, sales of a substantial number of shares of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could materially and adversely affect the prevailing market price of our common stock. Although we have applied to list our common stock on The Nasdaq Capital Market, we cannot assure you that there will be an active market for our common stock.

Of the shares to be outstanding immediately after the completion of this offering, we expect that the shares to be sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act. Certain of the remaining shares of our common stock outstanding after this offering will be subject to a 180-day lock-up period under the lock-up agreements as described in the *Underwriting* below. These restricted securities may be sold in the public market only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act.

Rule 144

Affiliate Resales of Restricted Securities

Affiliates of ours must generally comply with Rule 144 if they wish to sell any shares of our common stock in the public market, whether or not those shares are "restricted securities." "Restricted securities" are any securities acquired from us or one of our affiliates in a transaction not involving a public offering. All shares of our common stock issued prior to the closing of the offering made hereby, are considered to be restricted securities. The shares of our common stock sold in this offering are not considered to be restricted securities.

Non-Affiliate Resales of Restricted Securities

Any person or entity who is not an affiliate of ours and who has not been an affiliate of ours at any time during the three months preceding a sale is only required to comply with Rule 144 in connection with sales of restricted shares of our common stock. Subject to the lock-up agreements described below, those persons may sell shares of our common stock that they have beneficially owned for at least one year without any restrictions under Rule 144 immediately following the effective date of the registration statement of which this prospectus is a part.

Further, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time such person sells shares of our common stock, and has not been an affiliate of ours at any time during the three months preceding such sale, and who has beneficially owned such shares of our common stock for at least six months but less than a year, is entitled to sell such shares so long as there is adequate current public information, as defined in Rule 144, available about us.

Resales of restricted shares of our common stock by non-affiliates are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144, described above.

Rule 701

Rule 701 generally allows a stockholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of ours during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144.

Rule 701 also permits affiliates of ours to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701 and until expiration of the -day lock-up period described below.

Equity Incentive Awards

We intend to file a registration statement on Form S-8 under the Securities Act after the closing of this offering to register the shares of common stock that are issuable pursuant to our 2021 Plan, our 2019 Plan and 2018 Plan. The registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up arrangement described above, if applicable.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the ownership and disposition of our common stock but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Internal Revenue Code Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, so as to result in U.S. federal income tax consequences different from those set forth below. No ruling on the U.S. federal, state, or local tax considerations relevant to our operations or to the purchase, ownership or disposition of our shares, has been requested from the IRS or other tax authority. No assurance can be given that the IRS would not assert, or that a court would not sustain, a position contrary to any of the tax consequences described below.

This summary also does not address the tax considerations arising under the laws of any non-U.S., state or local jurisdiction, or under U.S. federal gift and estate tax laws, except to the limited extent set forth below. In addition, this discussion does not address tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

- banks, insurance companies or other financial institutions, regulated investment companies or real estate investment trusts;
- persons subject to the alternative minimum tax or Medicare contribution tax on net investment income;
- tax-exempt organizations or governmental organizations;
- controlled foreign corporations, passive foreign investment companies and corporations that accumulate earnings to avoid U.S. federal income tax;
- brokers or dealers in securities or currencies;
- traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;
- persons that own, or are deemed to own, more than five percent of our capital stock (except to the extent specifically set forth below);
- U.S. expatriates and certain former citizens or long-term residents of the U.S.;
- partnerships or entities classified as partnerships for U.S. federal income tax purposes or other pass-through entities (and investors therein);
- persons who hold our common stock as a position in a hedging transaction, "straddle," "conversion transaction" or other risk reduction transaction or integrated investment;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Internal Revenue Code; or
- persons deemed to sell our common stock under the constructive sale provisions of the Internal Revenue Code.

You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal estate or gift tax rules or under the laws of any state, local, non-U.S., or other taxing jurisdiction or under any applicable tax treaty.

Non-U.S. Holder Defined

For purposes of this discussion, you are a non-U.S. holder (other than a partnership) if you are any holder other than:

- an individual citizen or resident of the U.S. (for U.S. federal income tax purposes);
- a corporation or other entity taxable as a corporation created or organized in the U.S. or under the laws of the U.S., any state thereof, or the District of Columbia, or other entity treated as such for U.S. federal income tax purposes;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust (x) whose administration is subject to the primary supervision of a U.S. court and which has one or more "U.S. persons" (within the meaning of Section 7701(a)(30) of the Internal Revenue Code) who have the authority to control all substantial decisions of the trust or (y) which has made a valid election to be treated as a U.S. person.

In addition, if a partnership or entity classified as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our common stock, and partners in such partnerships, should consult their tax advisors.

Distributions

As described in "Dividend Policy," we have never declared or paid cash dividends on our common stock and do not anticipate paying any dividends on our common stock in the foreseeable future. However, if we do make distributions on our common stock, those payments will constitute dividends for U.S. tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent those distributions exceed both our current and our accumulated earnings and profits, they will constitute a return of capital and will first reduce your basis in our common stock, but not below zero, and then will be treated as gain from the sale of stock as described below under "— Gain on Disposition of Common Stock."

Subject to the discussion below on effectively connected income, backup withholding and foreign accounts, any dividend paid to you generally will be subject to U.S. withholding tax either at a rate of 30% of the gross amount of the dividend or such lower rate as may be specified by an applicable income tax treaty. In order to receive a reduced treaty rate, you must provide us with an IRS Form W-8BEN, IRS Form W-8BEN-E or other appropriate version of IRS Form W-8 certifying qualification for the reduced rate. A non-U.S. holder of shares of our common stock eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Dividends received by you that are effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, attributable to a permanent establishment maintained by you in the U.S.) are generally exempt from such withholding tax. In order to obtain this exemption, you must provide us with an IRS Form W-8ECI or other applicable IRS Form W-8 properly certifying such exemption. Such effectively connected dividends, although not subject to withholding tax, are taxed at the same graduated rates applicable to U.S. persons, net of certain deductions and credits. In addition, if you are a corporate non-U.S. holder, dividends you receive that are effectively connected with your conduct of a U.S. trade or business may also be subject to a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. You should consult your tax advisor regarding any applicable tax treaties that may provide for different rules.

Gain on Disposition of Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, you generally will not be required to pay U.S. federal income tax on any gain realized upon the sale or other disposition of our common stock unless:

- the gain is effectively connected with your conduct of a U.S. trade or business (and, if required by an applicable income tax treaty, the gain is attributable to a permanent establishment maintained by you in the U.S.);
- you are a non-resident alien individual who is present in the U.S. for a period or periods aggregating 183 days or more during the taxable year in which the sale or disposition occurs and certain other conditions are met; or
- our common stock constitutes a U.S. real property interest by reason of our status as a "U.S. real property holding corporation," ("USRPHC") for U.S. federal income tax purposes at any time within the shorter of (i) the five-year period preceding your disposition of our common stock, or (ii) your holding period for our common stock.

We believe that we are not currently and will not become a USRPHC for U.S. federal income tax purposes, and the remainder of this discussion so assumes. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of our other business assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if you actually or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock.

If you are a non-U.S. holder described in the first bullet above, you will be required to pay tax on the net gain derived from the sale under regular graduated U.S. federal income tax rates, and a corporate non-U.S. holder described in the first bullet above also may be subject to the branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty. If you are an individual non-U.S. holder described in the second bullet above, you will be required to pay a flat 30% tax (or such lower rate specified by an applicable income tax treaty) on the gain derived from the sale, which gain may be offset by U.S. source capital losses for the year (provided you have timely filed U.S. federal income tax returns with respect to such losses). You should consult any applicable income tax or other treaties that may provide for different rules.

Federal Estate Tax

Our common stock beneficially owned by an individual who is not a citizen or resident of the U.S. (as defined for U.S. federal estate tax purposes) at the time of their death will generally be includable in the decedent's gross estate for U.S. federal estate tax purposes, unless an applicable estate tax treaty provides otherwise. The test for whether an individual is a resident of the U.S. for U.S. federal estate tax purposes differs from the test used for U.S. federal income tax purposes. Some individuals, therefore, may be non-U.S. holders for U.S. federal income tax purposes, but not for U.S. federal estate tax purposes, and vice versa.

Backup Withholding and Information Reporting

Generally, we must report annually to the IRS the amount of dividends paid to you, your name and address and the amount of tax withheld, if any. A similar report will be sent to you. Pursuant to applicable income tax treaties or other agreements, the IRS may make these reports available to tax authorities in your country of residence.

Payments of dividends or of proceeds on the disposition of stock made to you may be subject to information reporting and backup withholding at a current rate of 28% unless you establish an exemption, for example, by properly certifying your non-U.S. status on an IRS Form W-8BEN, IRS Form W-8BEN-E or another appropriate version of IRS Form W-8.

Backup withholding is not an additional tax; rather, the U.S. federal income tax liability of persons subject to backup withholding will be reduced by the amount of tax withheld. If withholding results in an overpayment of taxes, a refund or credit may generally be obtained from the IRS, provided that the required information is furnished to the IRS in a timely manner.

Foreign Account Tax Compliance

The Foreign Account Tax Compliance Act ("FATCA") imposes withholding tax at a rate of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to "foreign financial institutions" (as specially defined under these rules), unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding the U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or otherwise establishes an exemption. FATCA also generally imposes a U.S. federal withholding tax of 30% on dividends on and gross proceeds from the sale or other disposition of our common stock paid to a "non-financial foreign entity" (as specially defined for purposes of these rules) unless such entity provides the withholding agent with a certification identifying certain substantial direct and indirect U.S. owners of the entity, certifies that there are none or otherwise establishes an exemption. The withholding provisions under FATCA generally apply to dividends on our common stock, and under current transition rules, are expected to apply with respect to the gross proceeds from the sale or other disposition of our common stock on or after January 1, 2019. An intergovernmental agreement between the U.S. and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock.

Each prospective investor should consult its tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

In connection with this offering, we will enter into an underwriting agreement with Roth Capital Partners, LLC as representative for the underwriters in this offering. Each underwriter named below has severally agreed to purchase from us, on a firm commitment basis, the number of shares of common stock set forth opposite its name below, at the public offering price, less the underwriting discount set forth on the cover page of this prospectus.

Underwriters	Number of Shares
Roth Capital Partners, LLC	
Kingswood Capital Markets, division of Benchmark Investments, Inc.	
Total	

The underwriting agreement will provide that the underwriters are obligated to purchase all of the common stock offered by this prospectus, other than those covered by the over-allotment option, if any shares of common stock are purchased. The underwriters are offering the shares when, as and if issued to and accepted by them, subject to a number of conditions. These conditions include, among other things, the requirements that no stop order suspending the effectiveness of the registration statement be in effect and that no proceedings for this purpose have been initiated or threatened by the SEC.

The representative of the underwriters has advised us that the underwriters propose to offer our common stock to the public at the offering price set forth on the cover page of this prospectus and to selected dealers at that price less a concession of not more than $ per share. The underwriters and selected dealers may re-allow a concession to other dealers, including the underwriters, of not more than $ per share. After completion of the public offering of the shares of common stock, the offering price, the concessions to selected dealers and the reallowance to their dealers may be changed by the underwriters.

We have been advised by the representative of the underwriters that the underwriters intend to make a market in our securities but that they are not obligated to do so and may discontinue making a market at any time without notice.

In connection with the offering, the underwriters or certain of the securities dealers may distribute prospectuses electronically.

Over-allotment Option

We have granted a 45-day option to the underwriters, exercisable one or more times in whole or in part, to purchase up to an additional shares of common stock on the same terms as the other shares being purchased by the underwriters from us, underwriting discounts and commissions to cover over-allotments, if any. The underwriters may exercise this option only to cover over-allotments made in connection with this offering. If the underwriters exercise this option in whole or in part, then the underwriters will be committed, subject to the conditions described in the underwriting agreement, to purchase the additional offered securities in proportion to each of their commitments set forth in the prior table.

Underwriters' Compensation

Discount

The underwriting discount is equal to the public offering price per share, less the amount paid by the underwriters to us per share. The underwriting discount was determined through an arms' length negotiation between us and the underwriters.

We have agreed to sell the shares of common stock to the underwriters at the initial offering price of $ per share, which represents the initial public offering price of the shares of common stock set forth on the cover page of this prospectus less a 7% underwriting discount. The following table shows the public offering price, total underwriting discounts and commissions to be paid to the underwriters, and the net proceeds to us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares of common stock.

	Per Share	Total Without Over-Allotment Option	Total With Over Allotment Option
Public offering price	$		
Underwriting discounts and commissions	$		
Net proceeds to us	$		

Expense Reimbursement

We have 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 $80,000. All fees already paid shall be reimbursable to us to the extent not actually incurred. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately $.

Warrants

Upon the closing of this offering, we have agreed to sell to the underwriters a warrant to purchase up to 5% of the number of shares of common stock sold in this offering. The warrant will be exercisable at a per share and warrant exercise price equal to 120% of the public offering price per share sold pursuant to this offering, subject to standard anti-dilution adjustments for share splits and similar transactions. The warrant will be exercisable at any time, and from time to time, in whole or in part, during the period commencing 180 days from the commencement of sales in this offering, and expiring five years from the commencement of sales in this offering. The warrant is also exercisable on a cashless basis. The warrants have been deemed compensation by FINRA and are therefore subject to a 180-day lock-up pursuant to FINRA Rule 5110(e)(1). Except as permitted by Rule 5110(e)(1), the underwriters (or permitted assignees under the Rule) will not sell, transfer, assign, pledge, or hypothecate the warrants or the securities underlying the warrants, nor will any, of them engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the option or the underlying securities for a period of 180 days from the commencement of sales under this prospectus. Although the warrants and the underlying shares have been registered in the registration statement of which this prospectus forms a part, we have also agreed to provide holders of the warrants one demand registration right and unlimited "piggy-back" registration rights with respect to the common stock underlying the warrants on only one occasion to register all of such underlying common shares at such time as we become eligible to file a resale registration statement on Form S-3. These registration rights apply to all of the securities directly and indirectly issuable upon exercise of the warrants, and shall expire on the fifth anniversary of the commencement of sales in this offering. We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants, other than underwriting commissions incurred and payable by the holders.

Lock-up Agreements

We have agreed with the underwriters that we will not, without the prior consent of Roth Capital Partners, LLC, as representative of the underwriters, directly or indirectly sell, offer, contract or grant any option to sell, pledge, transfer, or otherwise dispose of or enter into any transaction which may result in the disposition of any common stock or securities convertible into, exchangeable or exercisable for any common stock for a period of six months after the closing of this offering.

In addition, each of our executive officers and directors and our primary stockholder have agreed with the underwriters not to directly or indirectly sell, offer, contract or grant any option to sell, pledge, transfer (excluding intra-family transfers, transfers to a trust for estate planning purposes or to beneficiaries of officers, directors and shareholders upon their death), or otherwise dispose of or enter into any transaction which may result in the disposition of any common stock or securities convertible into, exchangeable or exercisable for any common stock, without the prior written consent of Roth Capital Partners, LLC, as representative of the underwriters, for a period of six months after the closing date of this offering.

Stabilization

In connection with this offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. Specifically, the underwriters may over-allot in connection with this offering by selling more shares than they are obligated to purchase under the underwriting agreement, creating a short position in our common stock. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares of common of stock over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares of common stock involved is greater than the number of shares in the over-allotment option. To close out a short position or to stabilize the price per share of our common stock the underwriters may bid for, and purchase, common stock in the open market. The underwriters may also elect to reduce any short position by exercising all or part of the over-allotment option. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of the common stock available for purchase in the open market as compared to the price at which it may purchase the common stock through the over-allotment option. If the underwriters sell more than could be covered by the over-allotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representative has repurchased common stock sold by or for the account of such underwriter in stabilizing or short covering transactions.

Finally, the underwriters may bid for, and purchase, common stock in market making transactions, including "passive" market making transactions as described below.

The foregoing transactions may stabilize or maintain the market price of our common stock at a price that is higher than the price that might otherwise exist in the absence of these activities. The underwriters are not required to engage in these activities, and may discontinue any of these activities at any time without notice. These transactions may be effected on a national securities exchange or otherwise.

In connection with this offering, the underwriters and selling group members, if any, or their affiliates may engage in passive market making transactions in common stock on a national securities exchange immediately prior to the commencement of sales in this offering, in accordance with Rule 103 of Regulation M under the Exchange Act. Rule 103 generally provides that:

- a passive market maker may not effect transactions or display bids for our common stock in excess of the highest independent bid price by persons who are not passive market makers; net purchases by a passive market maker on each day are generally limited to 30% of the passive market maker's average daily trading volume in our common share during a specified two-month prior period or 200 shares, whichever is greater, and must be discontinued when that limit is reached; and

- passive market making bids must be identified as such.

Passive market making may stabilize or maintain the market price of our common stock at a level above that which might otherwise prevail and, if commenced, may be discontinued at any time.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

Participation in Future Offerings

Until twelve months from the closing of the offering, the underwriters shall have a right of first refusal to act on our behalf as exclusive placement agent or sole book-running manager and sole lead managing underwriter, as applicable, for any offering of securities.

Determination of Public Offering Price

Prior to this offering, there has not been a public market for our shares. The public offering price of the shares offered by this prospectus has been determined by negotiation between us and the underwriters. Among the factors considered in determining the public offering price of the shares were:

- our history and our prospects;
- our financial information and historical performance;
- the industry in which we operate;
- the status and development prospects for our products and services;
- the experience and skills of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the common stock. That price is subject to change as a result of market conditions and other factors, and we cannot assure you that the common stock can be resold at or above the public offering price.

Listing

We have applied to list our common stock on the Nasdaq Capital Market under the symbol "UNCY."

Electronic Distribution

A prospectus in electronic format may be made available on websites or through other online services maintained by the underwriters of this offering, or by its affiliates. Other than the prospectus in electronic format, the information on the underwriters' website and any information contained in any other website maintained by an underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriters in their capacity as underwriters, and should not be relied upon by investors.

Other Relationships

The underwriters have informed us that they do not expect to confirm sales of our common stock offered by this prospectus to any accounts over which they exercise discretionary authority.

Some of the underwriters and their affiliates may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They may in the future receive customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers.

Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

This prospectus does not constitute an offer to sell to, or a solicitation of an offer to buy from, anyone in any country or jurisdiction (i) in which such an offer or solicitation is not authorized, (ii) in which any person making such offer or solicitation is not qualified to do so or (iii) in which any such offer or solicitation would otherwise be unlawful. No action has been taken that would, or is intended to, permit a public offer of the shares of common stock or possession or distribution of this prospectus or any other offering or publicity material relating to the shares of common stock in any country or jurisdiction (other than the U.S.) where any such action for that purpose is required. Accordingly, each underwriter has undertaken that it will not, directly or indirectly, offer or sell any shares of common stock or have in its possession, distribute or publish any prospectus, form of application, advertisement or other document or information in any country or jurisdiction except under circumstances that will, to the best of its knowledge and belief, result in compliance with any applicable laws and regulations and all offers and sales of shares of common stock by it will be made on the same terms.

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any common stock which are the subject of the offering contemplated herein may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to legal entities which are qualified investors as defined under the Prospectus Directive;
- by the underwriters to fewer than 100, or, if the Relevant Member State has implemented the relevant provisions of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

  provided that no such offer of common stock shall result in a requirement for us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

Each person in a Relevant Member State who receives any communication in respect of, or who acquires any common stock under, the offers contemplated here in this prospectus will be deemed to have represented, warranted and agreed to and with each underwriter and us that:

- it is a qualified investor as defined under the Prospectus Directive; and
- in the case of any common stock acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (i) the common stock acquired by it in the offering have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in the circumstances in which the prior consent of the representatives of the underwriters has been given to the offer or resale or (ii) where common stock have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of such common stock to it is not treated under the Prospectus Directive as having been made to such persons.

For the purposes of this representation and the provision above, the expression an "offer of common stock to the public" in relation to any common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any common stock to be offered so as to enable an investor to decide to purchase or subscribe for the common stock, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in each Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

United Kingdom

This prospectus has only been communicated or caused to have been communicated and will only be communicated or caused to be communicated as an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act of 2000 (the "FSMA")) as received in connection with the issue or sale of the common stock in circumstances in which Section 21(1) of the FSMA does not apply to us. All applicable provisions of the FSMA will be complied with in respect to anything done in relation to the common stock in, from or otherwise involving the United Kingdom.

Notice to Residents of Canada

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

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

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

LEGAL MATTERS

The validity of the issuance of the common stock offered by us in this offering will be passed upon for us by Sheppard, Mullin, Richter & Hampton LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Schiff Hardin LLP, Washington, District of Columbia.

EXPERTS

The financial statements of Unicycive Therapeutics, Inc. as of and for the years ended December 31, 2020 and 2019 included in this registration statement, of which this prospectus forms a part, have been audited by Mayer Hoffman McCann P.C., independent registered public accounting firm, as set forth in their report (which includes an explanatory paragraph related to the existence of substantial doubt about the Company's ability to continue as a going concern) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in auditing and accounting in giving said report.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the common stock offered by this prospectus. This prospectus, which is part of the registration statement, omits certain information, exhibits, schedules and undertakings set forth in the registration statement. For further information pertaining to us and our common stock, reference is made to the registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

In addition, registration statements and certain other filings made with the SEC electronically are publicly available through the SEC's website at *http://www.sec.gov*. The registration statement, including all exhibits and amendments to the registration statement, has been filed electronically with the SEC.

Upon completion of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act, and, accordingly, will be required to file annual reports containing financial statements audited by an independent public accounting firm, quarterly reports containing unaudited financial data, current reports, proxy statements and other information with the SEC. You will be able to inspect and copy such periodic reports, proxy statements and other information at the SEC's public reference room, and the website of SEC referred to above.

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, 2020 and 2019, and the related statements of operations, stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring losses and negative cash flows from operations and is dependent on additional financing to fund operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. 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
February 18, 2021

Unicycive Therapeutics, Inc.

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

	As of December 31, 2019	As of December 31, 2020	As of March 31, 2021 (unaudited)
Assets			
Current assets:			
Cash	$ 15	$ -	$ 147
Prepaid related party service fee	-	-	10
Deferred offering costs	-	200	272
Prepaid expenses and other current assets	4	4	84
Total current assets	19	204	513
Total assets	$ 19	$ 204	$ 513
Liabilities and stockholders' deficit			
Current liabilities:			
Accounts payable	$ 322	$ 184	$ 160
Related party service fee payable	108	9	-
Accrued liabilities	13	168	270
Convertible notes	-	1,528	2,790
Loan from stockholder	460	967	695
Government loan	-	19	-
Total current liabilities	903	2,875	3,915
Total liabilities	903	2,875	3,915
Commitments and contingencies (Note 7)			
Stockholders' deficit:			
Preferred stock: $0.001 par value per share—10,000,000 shares authorized at December 31, 2019, December 31, 2020, and March 31, 2021 (unaudited); no shares issued and outstanding at December 31, 2019, December 31, 2020, and March 31, 2021 (unaudited)	$ -	$ -	$ -
Common stock, $0.001 par value per share - 200,000,000 shares authorized at December 31, 2019, December 31, 2020, and March 31, 2021 (unaudited); 36,361,299 shares issued and outstanding at December 31, 2019, 36,610,216 shares issued and outstanding at December 31, 2020, and 37,615,632 shares issued and outstanding at March 31, 2021 (unaudited)	36	37	38
Additional paid-in capital	2,738	3,214	3,446
Accumulated deficit	(3,658)	(5,922)	(6,886)
Total stockholders' deficit	(884)	(2,671)	(3,402)
Total liabilities and stockholders' deficit	$ 19	$ 204	$ 513

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, 2019	Year Ended December 31, 2020	Three Months Ended March 31, 2020	Three Months Ended March 31, 2021
			(unaudited)	(unaudited)
Operating expenses:				
Research and development	$ 795	$ 1,015	$ 148	$ 450
General and administrative	1,168	1,005	194	281
Total operating expenses	1,963	2,020	342	731
Loss from operations	(1,963)	(2,020)	(342)	(731)
Other expenses:				
Interest expense	(139)	(244)	(2)	(252)
Loss on debt conversion	(63)	-	-	-
Gain on extinguishment of debt	-	-	-	19
Total other expenses	(202)	(244)	(2)	(233)
Net loss	$ (2,165)	$ (2,264)	$ (344)	$ (964)
Net loss per share, basic and diluted	$ (0.06)	$ (0.06)	$ (0.01)	$ (0.03)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	34,915,828	36,548,372	36,387,830	36,878,327

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.

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

	Common Stock		Preferred stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	33,762,335	$ 34	-	$ -	$ 253	$ (1,493)	$ (1,206)
Net loss	-	-	-	-	-	(2,165)	(2,165)
Issuance of common stock for cash	1,238,615	1	-	-	1,165	-	1,166
Conversion of convertible notes into common stock	1,159,065	1	-	-	1,101	-	1,102
Issuance of common stock for anti-dilution clause	149,762	-	-	-	145	-	145
Issuance of common stock in settlement of accounts payable	51,522	-	-	-	50	-	50
Stock-based compensation expense	-	-	-	-	24	-	24
Balance at December 31, 2019	36,361,299	36	-	-	2,738	(3,658)	(884)
Net loss	-	-	-	-	-	(2,264)	(2,264)
Issuance of common stock for cash	143,020	1	-	-	140	-	141
Issuance of common stock for anti-dilution clause	105,897	-	-	-	104	-	104
Stock-based compensation expense	-	-	-	-	232	-	232
Balance at December 31, 2020	36,610,216	$ 37	-	$ -	$ 3,214	$ (5,922)	$ (2,671)

	Common Stock		Preferred stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2019	36,361,299	$ 36	-	$ -	$ 2,738	$ (3,658)	$ (884)
Net loss (unaudited)	-	-	-	-	-	(344)	(344)
Issuance of common stock for cash (unaudited)	51,000	-	-	-	50	-	50
Issuance of common stock for anti-dilution clause (unaudited)	2,040	-	-	-	2	-	2
Stock-based compensation expense (unaudited	-	-	-	-	31	-	31
Balance at March 31, 2020 (unaudited)	36,414,339	$ 36	-	$ -	$ 2,821	$ (4,002)	$ (1,145)
Balance at December 31, 2020	36,610,216	$ 37	-	$ -	$ 3,214	$ (5,922)	$ (2,671)
Net loss (unaudited)	-	-	-	-	-	(964)	(964)
Issuance of common stock for exercise of options (unaudited)	1,005,416	1	-	-	30	-	31
Stock-based compensation expense (unaudited)	-	-	-	-	202	-	202
Balance at March 31, 2021 (unaudited)	37,615,632	$ 38	-	$ -	$ 3,446	$ (6,886)	$ (3,402)

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.

Statements of Cash Flows
(in thousands)

	Year Ended December 31, 2019	Year Ended December 31, 2020	Three Months Ended March 31, 2020	Three Months Ended March 31, 2021
			(unaudited)	(unaudited)
Cash flows from operating activities				
Net loss	$ (2,165)	$ (2,264)	$ (344)	$ (964)
Adjustments to reconcile net loss to net cash used in operating activities:				
R&D Expense for issuance of common stock for anti-dilution clause	145	104	2	-
Stock-based compensation expense	24	232	31	202
Convertible debt discount amortization	96	186	-	197
Loss on conversion	63	-	-	-
Convertible debt non-cash interest	43	53	-	56
Gain on government loan forgiven	-	-	-	(19)
Deferred compensation to CEO	313	396	135	37
Changes in assets and liabilities:				
Prepaid expense and other current assets	-	1	(18)	(80)
Related party service fee receivable	-	-	-	(10)
Accounts payable and accrued liabilities	308	(68)	128	(83)
Related party service fee payable	(3)	(99)	(7)	(9)
Net cash used in operating activities	(1,176)	(1,459)	(73)	(673)
Cash flows from financing activities				
Issuance of common stock	1,166	141	50	-
Proceeds from loan from stockholder	9	271	10	151
Proceeds from convertible notes	-	1,290	-	1,010
Repayment of loan from stockholder	(9)	(160)	-	(460)
Deferred offering costs	-	(117)	-	-
Proceeds from exercise of options	-	-	-	119
Proceeds from government loan	-	19	-	-
Net cash provided by financing activities	1,166	1,444	60	820
Net (decrease) increase in cash	(10)	(15)	(13)	147
Cash at the beginning of the period	25	15	15	-
Cash at the end of the period	$ 15	$ -	$ 2	$ 147
Supplemental cash flow information				
Deferred offering costs included in accrued liabilities	$ -	$ 82	$ -	$ 72
Accounts Payable settled with issuance of common stock	$ 50	$ -	$ -	$ -
Common stock issuance in conversion of convertible notes	$ 1,102	$ -	$ -	$ -
Cash paid for income taxes	$ 2	$ 1	$ -	$ -

See accompanying notes to the financial statements

Notes to the Financial Statements

(Information as of March 31, 2021 and for the three months ended March 31, 2020 and 2021 is unaudited)

1. Organization and Description of Business

Overview

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

The Company in-licensed the drug candidate UNI 494 from Sphaera Pharma Pte. Ltd, a Singapore-based corporation, ("Sphaera") (Note 3). UNI 494 is a pro-drug of Nicorandill that is being developed as a treatment for acute kidney injury.

In September 2018, the Company purchased a second drug candidate, Renazorb RZB 012 ("Renazorb") and its trademark, RENALAN, and various patents from Spectrum Pharmaceuticals, Inc. ("Spectrum") (Note 3). Renazorb is being developed for the treatment of hyperphosphatemia in patients with Chronic Kidney Disease ("CKD").

The Company continues to evaluate the licensing of additional technologies and drugs, targeting orphan diseases and other renal, liver and other metabolic diseases affecting fibrosis and inflammation.

Liquidity

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with governmental regulations and the need to obtain additional financing to fund operations. The Company's product candidates currently under development will require significant additional research and development efforts prior to commercialization. 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 March 31, 2021, December 31, 2020, and December 31, 2019, the Company had an accumulated deficit of $6.9 million, $5.9 million, and $3.7 million, respectively.

The Company expects to continue incurring losses for the foreseeable future and is required to raise additional capital 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 private equity offerings, debt financings, corporate collaborations or other means. From January 2021 through March 2021, the Company received an aggregate of $1.0 million upon the issuance of convertible notes. These funds were used primarily to settle outstanding accounts payable as well as $460,000 of the loan outstanding from the chief executive officer and principal stockholder. 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 $147,000 as of March 31, 2021, the Company believes that it will need funding before the end of the second quarter 2021 to continue operations, satisfy its obligations and fund the future expenditures that will be required to conduct the clinical and regulatory work to develop its product candidates.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. There is substantial doubt about the Company's ability to continue as a going concern for one year after the date that these financial statements are available to be issued, which is not alleviated by management's plans. The financial statements do not reflect any adjustments relating to the recoverability and reclassification of assets and liabilities that might be necessary from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the periods presented. Management believes that these estimates and assumptions are reasonable; however, actual results may differ and could have a material effect on future results of operations and financial position. Significant items subject to such estimates and assumptions include deferred tax asset valuation allowance, unrecognized tax benefits, stock-based compensation and fair value of Company's common stock. 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 planned Initial Public Offering ("IPO") are capitalized and recorded as a current asset on the balance sheets. The deferred offering costs will be offset against the proceeds received upon the closing of the planned IPO, which is expected to occur during 2021. In the event that the Company's plans for an IPO are terminated, all of the deferred offering costs will be written off within operating expenses in the Company's statements of operations. There were no deferred offering costs as of December 31, 2019, and there were $0.2 million and $0.3 million of deferred offering costs capitalized as of December 31, 2020 and March 31, 2021, respectively.

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, 2019, December 31, 2020, and March 31, 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 (which was nominal at December 31, 2020 and $147,000 at March 31, 2021) 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, 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 6).

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 underlying common stock on the date of grant.

Common Stock Valuations

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

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

Income Taxes

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

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

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 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.

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 the package of practical expedients available from the FASB. As a policy election, the Company chose to expense and amortize, on a straight line, the leases with terms less than 12 months. 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 1,348,750 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. 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 and was recorded to prepaid expenses and other current assets in accompanying balance sheets. Deliverables for the initial SOW are expected to be completed by December 31, 2021.

4. Balance Sheet Components

Accounts payable as of December 31, 2019 and 2020, and March 31, 2021 consists of the following (in thousands):

	As of December 31, 2019	As of December 31, 2020	As of March 31, 2021
Trade accounts payable	$ 288	$ 183	$ 160
Credit card liability	34	1	-
Total	$ 322	$ 184	$ 160

5. Debt

Convertible Notes

In January through March 2021, the Company issued convertible notes (the "2021 Notes") in the aggregate principal amount of $1,010,000. The 2021 Notes bear interest at a rate of 12% per annum, payable at maturity, and mature between January and March, 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 is accreting the carrying amount of the 2021 Notes to the settlement amount through maturity. As of March 31, 2021, unpaid and accrued interest of $17,000 as well as debt discount accretion expense of approximately $60,000 is included with the Convertible notes on the balance sheet.

In July through November 2020, the Company issued convertible notes (the "2020 Notes") in the aggregate principal amount of $1,290,000. The 2020 Notes bear interest at a rate of 12% per annum, payable at maturity, and mature between July and November, 2021. The 2020 Notes shall automatically convert into shares of the Company's common stock upon the closing of a financing pursuant to which the Company receives gross proceeds of at least $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 of March 31, 2021, unpaid and accrued interest of $91,000 as well as debt discount accretion expense of approximately $323,000 is included with the convertible notes on the balance sheet.

In 2017 and 2018, the Company raised $550,000 from the issuance of twelve convertible promissory notes (the "2018 Notes"). The 2018 Notes bear interest at 10% per annum which was payable at maturity. The 2018 Notes' principal and interest were due and payable on written demand by the majority of the 2018 Note holders on the two-year anniversary of the first 2018 Note issued. The first 2018 Note was issued on October 5, 2017 and, accordingly, all 2018 Notes would have matured on October 5, 2019. In the event the Company consummated an equity financing with an aggregate sales price of not less than $500,000, then the aggregate outstanding principal and unpaid interest would automatically convert into shares of the Company's common stock. The per-share price of the conversion would be equal to 75% of the price per share paid by the cash purchasers of the common stock sold in the financing.

The Company accounted for the 2018 Notes as stock-settled debt and accreted the carrying amount of the 2018 Notes to the settlement amount through maturity. On July 31, 2019, all 2018 Notes principal and accrued interest were converted into 1,159,065 shares of common stock upon the consummation of a 2019 equity financing in excess of $500,000. The Company recorded, as part of the conversion of the debt, a loss on conversion of $63,000 included in other expenses.

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 period ended March 31, 2021.

6. Related Party Transactions

Loan from Chief Executive Officer and Stockholder

As of March 31, 2021, December 31, 2020, and December 31, 2019, the current liability loan from a stockholder of approximately $695,000, $967,000, and $460,000, respectively, represents primarily the accumulation of deferred compensation due to the chief executive officer and stockholder. This amount bears no interest and is repayable on demand.

Service agreement with Globavir

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 program. The Service Agreement provides Globavir the right to receive $50,000 per month for such services through December 31, 2019 and $10,000 per month commencing on January 1, 2020. As of December 31, 2019 and December 31, 2020, respectively, $108,000 and $9,000 was payable to Globavir for such service fees. As of March 31, 2021, $10,000 was prepaid to Globavir for such service fees. Amounts incurred by the Company under the Service Agreement were $600,000 and $120,000 for the years ended December 31, 2019 and 2020. Amounts incurred by the Company under the Service Agreement were $30,000 and $30,000 for the three months ended March 31, 2020 and March 31, 2021, respectively, and are included in operating expenses in the statements of operations. The initial amended term of the agreement ended on December 31, 2020, and unless terminated, the Service Agreement automatically renews for successive one month periods after the initial termination date.

Common stock purchase agreement and services agreement

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 267,380 shares of the Company's common stock, valued at $0.003 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.

7. Commitments and Contingencies

Contingencies

The Company is subject to claims and legal proceedings that arise in the ordinary course of business. Such matters are inherently uncertain, and there can be no guarantee that the outcome of any such matter will be decided favorably to the Company or that the resolution of any such matter will not have a material adverse effect upon the Company's financial statements. The Company currently has no pending claims or legal proceedings.

In September 2020, the Company signed an engagement letter (the "Benchmark Agreement") with The Benchmark Company LLC ("Benchmark") to act as the lead or managing underwriter in connection with the Company's planned initial public offering. In connection with this agreement the Company has agreed to pay a nonaccountable expense allowance to Benchmark equal to 1.0% of the gross proceeds received in the Company's planned initial public offering. In addition to the non-accountable expense allowance, the Company has also agreed to pay or reimburse the underwriters for certain of the underwriters' out-of-pocket expenses relating to the offering, including all reasonable fees and expenses of the underwriters' outside legal counsel, and background checks, which shall not exceed in the aggregate $132,500. In connection with this agreement the Company has paid $25,000 in costs through December 31, 2020 which was recorded as deferred offering costs on the accompanying balance sheet.

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

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. The Company intends to enter into new indemnification agreements with its officers and directors to further expand coverage of these individuals upon the Company's completion of an initial public offering.

8. Stockholders' Deficit

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

During the three months ended March 31, 2021, employees and consultants exercised a total of 1,650,000 stock options and the Company received $119,000 in proceeds. A portion of these options were exercised early (prior to vesting), and as of March 31, 2021, 644,584 of the options remained unvested. Proceeds received related to the unvested options of $88,000 at March 31, 2021 were recorded 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 Company issued 1,005,416 shares of common stock to employees and consultants, representing the vested portion of the exercises at March 31, 2021.

During the three months ended March 31, 2020, the Company issued 51,000 shares to investors in exchange of cash at $0.98 per share.

During the year ended December 31, 2020, the Company issued 143,020 shares to investors in exchange of cash at $0.98 per share and 105,897 shares to Spectrum following its anti-dilution provision (Note 3).

During 2019, the Company issued 1,238,615 shares to investors for a total of $1,166,000 with prices ranging from $0.83 to $0.98 per share, 1,159,065 shares upon conversion of its convertible notes (Note 5), 149,762 shares to Spectrum following its anti-dilution provision (Note 3) and 51,522 shares to a vendor for settlement of an accounts payable for a total of $50,000.

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, 2019 and 2020, the Company had 10,000,000 shares of preferred stock authorized, par value of $0.001 per share and no shares of preferred stock were issued or outstanding. As of March 31, 2021, the Company had 10,000,000 shares of preferred stock authorized, par value of $0.001 per share and no shares of preferred stock were issued or outstanding.

9. Stock-based Compensation

In 2018, the Company adopted the 2018 Equity Incentive Plan ("2018 Plan") which allows 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, 2019, December 31, 2020, and March 31, 2021, respectively, 2,000,000 shares are authorized for issuance and 75,000 shares are available for future grant under the 2018 Plan.

In October 2019, the Company adopted the 2019 Stock Option Plan ("2019 Plan") which allows 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, 1,000,000 shares were authorized for issuance and 325,000 shares were available for future grant under the 2019 Plan. On April 6, 2020 the Company increased the shares authorized for issuance to 1,500,000 shares total. On February 17, 2021, the Company increased the shares authorized for issuance to 7,600,000 shares total. As of March 31, 2021, 5,577,000 shares were available for future grant under the 2019 Plan.

The following table summarizes activity for stock options under both plans for the years ended December 31, 2019 and 2020 and for the three months ended March 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, 2018	1,925,000	0.003	9.66	1,284
Options granted	675,000	0.76		
Outstanding, December 31, 2019	2,600,000	0.20	8.56	2,029
Options granted	780,000	0.76		
Outstanding, December 31, 2020	3,380,000	0.33	8.28	2,201
Options granted	568,000	1.63		
Options exercised	(1,005,416)	0.03		
Outstanding, March 31, 2021	2,942,584	0.68	7.73	2,790
Shares vested and exercisable as of December 31, 2019	697,918	$ -	8.66	$ 2,029
Shares vested and exercisable as of December 31, 2020	1,339,204	$ 0.12	7.85	$ 1,151
Shares vested and exercisable as of March 31, 2021	610,163	$ 0.45	8.13	$ 719

The grant date fair value of options granted during the years ended December 31, 2020 and 2019 was $0.8 million and $0.5 million, respectively. The grant date fair value of options granted during the three months ended March 31, 2021 was $0.7 million.

As of December 31, 2020 and 2019, the unrecognized compensation costs related to outstanding stock options was $0.9 million and $0.5 million, respectively, which is expected to be recognized as expense over approximately 3.7 years and 3.8 years, respectively. As of March 31, 2021, the unrecognized compensation cost related to outstanding stock options was $1.5 million, which is expected to be recognized as expense over approximately 2.6 years.

The Company has recorded stock-based compensation expense, allocated by functional cost as follows for the years ended December 31, 2019 and 2020 and for the three months ended March 31, 2020 and 2021 (in thousands):

	Years Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020 (unaudited)	2021 (unaudited)
Research and development	$ 14	$ 174	$ 17	$ 184
General and administrative	10	58	14	18
Total stock-based compensation	$ 24	$ 232	$ 31	$ 202

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 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. 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, 2019 and 2020 and for the three months ended March 31, 2020 and 2021:

	Year Ended December 31, 2019	Year Ended December 31, 2020	Three Months Ended March 31, 2020 (unaudited)	Three Months Ended March 31, 2021 (unaudited)
Expected volatility	91.00%	114.00%	-%	104.00 – 105.00%
Risk-free interest rate	1.61%	0.44 - 0.51%	-%	0.92%
Dividend yield	-%	-%	-%	-%
Expected term	6.25 years	6.25 years	- years	5.13 – 6.25 years

10. 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, 2019 and 2020 is as follows:

	Year Ended December 31, 2019	Year Ended December 31, 2020
Income taxes (benefit) at statutory rates	21.00%	21.00%
State income tax (benefit), net of federal benefit	5.90	6.20
Change in valuation allowance	(23.10)	(26.30)
Interest on convertible notes	(1.90)	(2.20)
Others	(1.90)	1.30
Effective income tax rate	-%	-%

For the years ended December 31, 2019 and 2020, the Company did not record a deferred income tax expense or benefit. Income tax expense has been nominal for the years ended December 31, 2019 and 2020.

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, 2019 and 2020 are shown below (in thousands):

	December 31, 2019	December 31, 2020
Deferred tax assets:		
Stock-based compensation	$ 7	$ 71
Net operating losses carryforwards	690	1,072
Depreciation and Amortization	-	63
Accrued expenses	164	251
Gross deferred tax assets	861	1,457
Less: Valuation allowance	(861)	(1,457)
Deferred tax assets, net of valuation allowance	$ -	$ -

The valuation allowance increased by $0.6 million during the year ended December 31, 2020. 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, 2020, the Company had available Federal and California net operating loss carryforwards of approximately $3.8 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, 2020, the Company had research and development credit carryforwards of approximately $900 and $29,000 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, 2020 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.

As of December 31, 2019 and 2020, the total unrecognized tax benefit was approximately $12,000 and $29,000, 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, 2020, 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 2016 and forward remain open to examination due to the carryover of NOL carryforwards. There are no ongoing examinations by taxing authorities at this time.

11. 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, 2019	Year Ended December 31, 2020	Three Months Ended March 31, 2020	Three Months Ended March 31, 2021
Numerator:			(unaudited)	(unaudited)
Net loss	$ (2,165)	$ (2,264)	$ (344)	$ (964)
Denominator:				
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	34,915,828	36,548,372	36,387,830	36,878,327
Net loss per share attributable to common stockholders, basic and diluted	$ (0.06)	$ (0.06)	$ (0.01)	$ (0.03)

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, 2019	Year Ended December 31, 2020	Three Months Ended March 31, 2020	Three Months Ended March 31, 2021
			(unaudited)	(unaudited)
Options to purchase common stock	2,600,000	3,380,000	3,380,000	2,942,584
Total	2,600,000	3,380,000	3,380,000	2,942,584

12. Subsequent Events

On April 5, 2021, the Company engaged Roth Capital Partners as lead underwriter for the planned initial public offering. Under the terms of engagement, the Company will pay Roth Capital Partners 7% underwriting fee and will also grant warrants for the purchase of the Company's shares of common stock in an amount equal to 5.0% of the number of shares of common stock of the Company issued to the investors in the IPO. Roth Capital Partners will serve as sole book-running manager, and Kingswood Capital Markets (a division of Benchmark Investments, Inc.) will serve as lead manager. The Benchmark Company LLC will provide capital markets and other advisory services and guidance to the Company for a fixed fee of $150,000 to be paid upon completion of the planned IPO.

During May, 2021, the Company issued convertible promissory notes in the aggregate principal amount of approximately $88,000. The notes bear interest at a rate of 12% per annum and mature in May 2022. The 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 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.

Shares

Common Stock

Sole Book-Running Manager

Roth Capital Partners

Lead Manager

KINGSWOOD CAPITAL MARKETS
division of Benchmark Investments, Inc.

Prospectus

, 2021

Until , 2021 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

PART II—INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth all expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of the securities being registered. All the amounts shown are estimates except the SEC registration fee and the FINRA filing fee.

	Amount to be paid
SEC registration fee	$ 3,961
FINRA filing fee	$ 4,130
The Nasdaq Capital Market initial listing fee	$ 55,000
Transfer agent and registrar fees	$ *
Accounting fees and expenses	$ *
Legal fees and expenses	$ *
Printing and engraving expenses	$ *
Miscellaneous	$ *
Total	**$ ***

* To be filed by amendment.

Item 14. Indemnification of Directors and Officers

Section 102 of the DGCL permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our Amended and Restated Certificate of Incorporation provides that no director of the Company shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the DGCL prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the DGCL provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws will provide indemnification for our directors and officers to the fullest extent permitted by the DGCL. We will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws will provide that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

Prior to the consummation of this offering, we intend to enter into separate indemnification agreements with each of our directors and executive officers. Each indemnification agreement shall provide, among other things, for indemnification to the fullest extent permitted by law and our Amended and Restated Certificate of Incorporation against any and all expenses, judgments, fines, penalties and amounts paid in settlement of any claim. The indemnification agreements shall provide for the advancement or payment of all expenses to the indemnitee and for the reimbursement to us if it is found that such indemnitee is not entitled to such indemnification.

In addition, we carry officer and director insurance for claims based on acts or omissions of such officers and directors in their capacity as such.

In any underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act against certain liabilities.

Item 15. Recent Sales of Unregistered Securities

Set forth below is information regarding securities issued by us since during the prior three years that were not registered under the Securities Act.

2021

From January to May 19, 2021, the Company issued convertible promissory notes in the aggregate principal amount of $1,098,000.

In March 2021, consultants and one employee exercised stock options in exchange for a total of 1,005,416 shares of our common stock.

In March 2021 we issued an aggregate of 568,000 options to purchase our common stock to consultants under our 2019 Stock Option Plan.

2020

From February to May 2020, we issued an aggregate of 143,020 shares of common stock in a private placement to accredited investors.

From March to September 2020, we issued an aggregate of 105,897 shares of common stock pursuant to an anti-dilution provision under an Assignment and Asset Purchase Agreement (the "Renazorb Purchase Agreement") with Spectrum Pharmaceuticals, Inc. ("Spectrum").

From April to July 2020 we issued an aggregate of 780,000 options to purchase our common stock to consultants under our 2019 Stock Option Plan.

From July to November 2020, we issued aggregate principal amount of $1,290,000 in convertible promissory notes to accredited investors.

2019

During 2019 we issued a total of 1,238,615 shares of common stock in private placements to accredited investors.

In July 2019, we issued 1,159,065 shares of common stock in conversion of certain outstanding promissory notes.

From March to December 2019, we issued an aggregate of 149,762 shares of common stock pursuant to an anti-dilution provision under the Renazorb Purchase Agreement with Spectrum.

In July 2019, we issued 51,522 shares of common stock in settlement of certain accounts payable with a vendor.

In October and December 2019, we issued a total of 675,000 options to purchase common stock under our 2019 Stock Option Plan.

2018

During 2018, we issued a total of 8,521,205 shares of common stock in private placements to accredited investors.

In September 2018, we issued 1,348,750 shares of common stock in connection with the consummation of the Renazorb Purchase Agreement with Spectrum.

In June 2018, we issued 267,380 shares of common stock to Globavir BioSciences, Inc. ("Globavir"), a related party, pursuant to a services agreement.

From January to July 2018, we issued an aggregate principal amount of $550,000 in convertible promissory notes to accredited investors.

In July 2018, we issued a total of 1,925,000 options to purchase common stock under our 2018 Equity Incentive Plan.

Item 16. Exhibits and Financial Statement Schedules

EXHIBIT INDEX

Exhibit No.	Description
1.1*	Form of Underwriting Agreement
3.1*	Certificate of Incorporation
3.2*	Certificate of Amendment to the Certificate of Incorporation
3.3*	Bylaws of Unicycive Therapeutics, Inc.
3.4	Form of Amended and Restated Certificate of Incorporation, to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part
3.5	Form of Amended and Restated Bylaws, to be effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part
4.1	Specimen Stock Certificate evidencing the shares of common stock
5.1*	Opinion of Sheppard, Mullin, Richter & Hampton LLP
10.1+*	2018 Equity Incentive Plan
10.2+*	2019 Stock Option Plan
10.3+	2021 Omnibus Equity Incentive Plan
10.4*	Assignment and Asset Purchase Agreement by and between the Company and Spectrum Pharmaceuticals, Inc., dated September 20, 2018
10.5*	Exclusive License Agreement by and between the Company and Sphaera Pharma Pte. Ltd., dated October 1, 2017
10.6*	Service Agreement by and between the Company and Globavir Biosciences, Inc. dated July 1, 2017
10.7+	Employment Agreement by and between the Company and Shalabh Gupta, M.D., dated May 18, 2021
10.8+	Employment Agreement by and between the Company and Pramod Gupta, M.D., dated March 22, 2021
10.9+	Amendment to Employment Agreement by and between the Company and Pramod Gupta, M.D., dated April 28, 2021
10.10#	Master Services Agreement, dated February 8, 2021, by and between Unicycive Therapeutics, Inc. and Ascent Development Services, Inc.
23.1	Consent of Mayer Hoffman McCann P.C., independent registered public accounting firm
23.2*	Consent of Sheppard, Mullin, Richter & Hampton, LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included on the signature page to this registration statement)
99.1*	Consent of Brigitte Schiller, M.D. to be named as a director upon completion of the offering

* To be filed by amendment.
\+ 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).

Financial Statement Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

b) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of Unicycive Therapeutics, Inc. pursuant to the foregoing provisions, or otherwise, Unicycive Therapeutics, Inc. has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by Unicycive Therapeutics, Inc. of expenses incurred or paid by a director, officer or controlling person of Unicycive Therapeutics, Inc. in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, Unicycive Therapeutics, Inc. will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction, the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

(c) The undersigned hereby further undertakes that:

(1) For purposes of determining any liability under the Securities Act the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by Unicycive Therapeutics, Inc. pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Los Altos, State of California, on the 21st day of May, 2021.

UNICYCIVE THERAPEUTICS, INC.

By: /s/ Shalabh Gupta, M.D.
Shalabh Gupta, M.D.
Chief Executive Officer,
President and Chairman

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Shalabh Gupta, M.D., his true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for him and in his name, place and stead, in any and all capacities to sign any or all amendments (including, without limitation, post-effective amendments) to this Registration Statement, any related Registration Statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and any or all pre- or post-effective amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that said attorney-in-fact and agent, or any substitute or substitutes for him, may lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Act of 1933, as amended, the following persons in the capacities and on the dates indicated have signed this Registration Statement below.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated below.

Signature	Title	Date
/s/ Shalabh Gupta, M.D. Shalabh Gupta, M.D.	Chief Executive Officer, President and Chairman *(Principal Executive Officer)*	May 21, 2021
/s/ John Townsend John Townsend	Chief Financial Officer *(Principal Financial and Accounting Officer)*	May 21, 2021
/s/ John Ryan, M.D., Ph.D. John Ryan, M.D., Ph.D.	Director	May 21, 2021
/s/ Sandeep Laumas, M.D. Sandeep Laumas, M.D.	Director	May 21, 2021

AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
of
UNICYCIVE THERAPEUTICS, INC.

ARTICLE I

The name of the corporation is Unicycive Therapeutics, Inc. (the "**Corporation**").

ARTICLE II

The address of the registered office of the Corporation in the State of Delaware is Corporation Trust Center, 1209 Orange Street, Wilmington, New Castle County, Delaware 19801. The name of its registered agent at such address is The Corporation Trust Company.

ARTICLE III

The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

ARTICLE IV

A. The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 200,000,000 shares of common stock, $0.0001 par value per share ("**Common Stock**"), and (ii) 10,000,000 shares of preferred stock, $0.001 par value per share ("**Preferred Stock**").

B. The Preferred Stock may be issued from time to time in one or more series. The Board of Directors of the Company (the "**Board**") is hereby expressly authorized, by filing a certificate ("**Certificate of Designation**") pursuant to the DGCL, to provide for the issue of any or all of the unissued and undesignated shares of the Preferred Stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences and relative, participating, optional, or other rights and such qualifications, limitations or restrictions thereof as shall be stated and expressed in the resolution or resolutions adopted by the Board providing for the issuance of such shares and as may be permitted by the DGCL. The Board of Directors is also expressly authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series. The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of the stock of the Company entitled to vote thereon, without a separate vote of the holders of the Preferred Stock, or of any series thereof, unless a vote of any such holders is required pursuant to the terms of any certificate of designation filed with respect to any series of Preferred Stock.

Each outstanding share of Common Stock shall entitle the holder thereof to one vote on each matter properly submitted to the stockholders of the Company for their vote; *provided*, *however*, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (this "**Certificate of Incorporation**") (including any Certificate of Designation filed with respect to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series of Preferred Stock are entitled, either separately or together as a class with the holders of one or more other series of Preferred Stock, to vote thereon by law or pursuant to this Certificate of Incorporation (including any Certificate of Designation filed with respect to any series of Preferred Stock).

C. Upon the filing (the "**Effective Time**") of this Certificate of Incorporation, each [__] ([__]) shares of the Corporation's Common Stock, issued and outstanding immediately prior to the Effective Time (the "**Old Common Stock**") shall automatically without further action on the part of the Corporation or any holder of Old Common Stock, be reclassified, combined, converted and changed into one (1) fully paid and nonassessable share of common stock, par value of $0.0001 per share (the "**New Common Stock**"), subject to the treatment of fractional share interests as described below (the "**reverse stock split**"). The conversion of the Old Common Stock into New Common Stock will be deemed to occur at the Effective Time. From and after the Effective Time, certificates representing the Old Common Stock shall represent the number of shares of New Common Stock into which such Old Common Stock shall have been converted pursuant to this Certificate of Incorporation. Holders who otherwise would be entitled to receive fractional share interests of New Common Stock upon the effectiveness of the reverse stock split shall be entitled to receive a whole share of New Common Stock in lieu of any fractional share created as a result of such reverse stock split and shall be rounded up to the nearest whole share.

ARTICLE V

In furtherance and not in limitation of the powers conferred by the DGCL, subject to the rights of the holders of any series of Preferred Stock that may be designated from time to time, the Board is expressly authorized to adopt, amend or repeal the bylaws of the Corporation (the "**Bylaws**"), subject to the power of the stockholders of the Corporation to alter or repeal any Bylaws whether adopted by them or otherwise; *provided*, *however*, that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by this Certificate of Incorporation (including any Certificate of Designation that may be filed from time to time), the affirmative vote of holders of not less than sixty-six and two-thirds percent (66 2/3%) of the votes of all outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, considered for purposes hereof as a single class, shall be required for the stockholders to adopt new Bylaws or to alter, amend or repeal the Bylaws.

ARTICLE VI

A. The management of the business and the conduct of the affairs of the Corporation shall be vested in the Board. The number of directors which shall constitute the whole Board shall be fixed exclusively by one or more resolutions adopted from time to time by the Board.

B. The Board or any individual director may be removed from office only for cause at a meeting of stockholders called for that purpose, by the affirmative vote of the holders of at least at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all the then outstanding shares of voting stock of the Corporation entitled to vote at an election of directors, voting together as a single class.

C. Any vacancies on the Board resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors shall, unless the Board determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders, except as otherwise provided by law and or by this Certificate of Incorporation or any Certificate of Designation that may be filed with respect to a series of Preferred Stock, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified.

D. The directors of the Corporation need not be elected by written ballot unless the Bylaws so provide.

E. There shall be no cumulative voting in the election of directors.

ARTICLE VII

A. Subject to the rights of the holders of any series of Preferred Stock or any other class of stock or series thereof having a preference over the Common Stock as to dividends or upon liquidation, any action required or permitted to be taken by the stockholders of the Corporation must be effected at a duly called annual or special meeting of the stockholders of the Corporation. The taking of any action by written consent of the stockholders in lieu of a meeting of the stockholders is specifically denied.

B. Special meetings of the stockholders of the Corporation may be called, for any purpose or purposes, by the Secretary of the Corporation at the direction of the Board, pursuant to a resolution adopted by a majority of the entire Board, but such special meetings may not be called by any other person or persons.

C. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner provided in the Bylaws of the Corporation.

ARTICLE VIII

A. To the fullest extent permitted by the DGCL, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the DGCL is amended after approval by the stockholders of this Article VIII to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL as so amended.

B. Any repeal or modification of the foregoing provisions of this Article VIII shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

ARTICLE IX

Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the Corporation, (b) any action asserting a claim of breach of a fiduciary duty owed by any director, officer, employee or agent of the Corporation to the Corporation or the Corporation's stockholders, (c) any action asserting a claim arising pursuant to any provision of the DGCL, this Certificate of Incorporation or the Bylaws, or (d) any action asserting a claim that is governed by the internal affairs doctrine, in each such case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein and the claim not being one 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. Any person purchasing or otherwise acquiring any interest in any shares of the Corporation's capital stock shall be deemed to have notice of, and to have consented to the provisions of this Article IX.

Unless the Corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Article IX.

* * *

AMENDED AND RESTATED BYLAWS *of* UNICYCIVE THERAPEUTICS, INC.

ARTICLE I - CORPORATE OFFICES

1.1 REGISTERED OFFICE.

The registered office of Unicycive Therapeutics, Inc. (the "Corporation"), shall be fixed in the Corporation's certificate of incorporation, as the same may be amended from time to time (the "certificate of incorporation").

1.2 OTHER OFFICES.

The Corporation's board of directors (the "Board") may at any time establish other offices at any place or places where the Corporation is qualified to do business.

ARTICLE II - MEETINGS OF STOCKHOLDERS

2.1 PLACE OF MEETINGS.

Meetings of stockholders shall be held at any place, within or outside the State of Delaware, designated by the Board. The Board may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a)(2) of the General Corporation Law of the State of Delaware (the "DGCL"). In the absence of any such designation or determination, stockholders' meetings shall be held at the Corporation's principal executive office.

2.2 ANNUAL MEETING.

The Board shall designate the date and time of the annual meeting. At the annual meeting, directors shall be elected and other proper business properly brought before the meeting in accordance with Section 2.4 may be transacted.

2.3 SPECIAL MEETING.

A special meeting of the stockholders may be called at any time by the Secretary of the Corporation at the direction of the Board, pursuant to a resolution adopted by a majority of the entire Board, but such special meetings may not be called by any other person or persons.

No business may be transacted at such special meeting other than the business specified in such notice to stockholders. Nothing contained in this paragraph of this Section 2.3 shall be construed as limiting, fixing, or affecting the time when a meeting of stockholders called by action of the Board may be held.

2.4 ADVANCE NOTICE PROCEDURES FOR BUSINESS BROUGHT BEFORE A MEETING.

(i) At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be (a) specified in a notice of meeting given by or at the direction of the Board, (b) if not specified in a notice of meeting, otherwise brought before the meeting by or at the direction of the Board or the chairperson of the Board, or (c) otherwise properly brought before the meeting by a stockholder present in person who (A)(1) was a beneficial owner of shares of the Corporation both at the time of giving the notice provided for in this Section 2.4 and at the time of the meeting, (2) is entitled to vote at the meeting and (3) has complied with this Section 2.4 in all applicable respects, or (B) properly made such proposal in accordance with Rule 14a-8 under the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (as so amended and inclusive of such rules and regulations, the "Exchange Act"). The foregoing clause (c) shall be the exclusive means for a stockholder to propose business to be brought before an annual meeting of the stockholders. The only matters that may be brought before a special meeting are the matters specified in the notice of meeting given by or at the direction of the person calling the meeting pursuant to Section 2.3 of these bylaws, and stockholders shall not be permitted to propose business to be brought before a special meeting of the stockholders. For purposes of this Section 2.4, "present in person" shall mean that the stockholder proposing that the business be brought before the annual meeting of the Corporation, or, if the proposing stockholder is not an individual, a qualified representative of such proposing stockholder, appear at such annual meeting. A "qualified representative" of such proposing stockholder shall be, if such proposing stockholder is (x) a general or limited partnership, any general partner or person who functions as a general partner of the general or limited partnership or who controls the general or limited partnership, (y) a corporation or a limited liability company, any officer or person who functions as an officer of the corporation or limited liability company or any officer, director, general partner or person who functions as an officer, director or general partner of any entity ultimately in control of the corporation or limited liability company or (z) a trust, any trustee of such trust. Stockholders seeking to nominate persons for election to the Board must comply with Section 2.5 of these bylaws, and this Section 2.4 shall not be applicable to nominations except as expressly provided in Section 2.5 of these bylaws.

(ii) Without qualification, for business to be properly brought before an annual meeting by a stockholder, the stockholder must (a) provide Timely Notice (as defined below) thereof in writing and in proper form to the Secretary of the Corporation and (b) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.4. To be timely, a stockholder's notice must be delivered to, or mailed and received at, the principal executive offices of the Corporation not less than ninety (90) days nor more than one hundred twenty (120) days prior to the one-year anniversary of the preceding year's annual meeting; *provided*, *however*, that if the date of the annual meeting is more than thirty (30) days before or more than sixty (60) days after such anniversary date, notice by the stockholder to be timely must be so delivered, or mailed and received, not later than the ninetieth (90th) day prior to such annual meeting or, if later, the tenth (10th) day following the day on which public disclosure of the date of such annual meeting was first made (such notice within such time periods, "Timely Notice"). In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the giving of Timely Notice as described above.

(iii) To be in proper form for purposes of this Section 2.4, a stockholder's notice to the Secretary shall set forth:

(a) As to each Proposing Person (as defined below), (A) the name and address of such Proposing Person (including, if applicable, the name and address that appear on the Corporation's books and records); and (B) the class or series and number of shares of the Corporation that are, directly or indirectly, owned of record or beneficially owned (within the meaning of Rule 13d-3 under the Exchange Act) by such Proposing Person, except that such Proposing Person shall in all events be deemed to beneficially own any shares of any class or series of the Corporation as to which such Proposing Person has a right to acquire beneficial ownership at any time in the future (the disclosures to be made pursuant to the foregoing clauses (A) and (B) are referred to as "Stockholder Information");

(b) As to each Proposing Person, (A) the full notional amount of any securities that, directly or indirectly, underlie any "derivative security" (as such term is defined in Rule 16a-1(c) under the Exchange Act) that constitutes a "call equivalent position" (as such term is defined in Rule 16a-1(b) under the Exchange Act) ("Synthetic Equity Position") and that is, directly or indirectly, held or maintained by such Proposing Person with respect to any shares of any class or series of shares of the Corporation; *provided* that, for the purposes of the definition of "Synthetic Equity Position," the term "derivative security" shall also include any security or instrument that would not otherwise constitute a "derivative security" as a result of any feature that would make any conversion, exercise or similar right or privilege of such security or instrument becoming determinable only at some future date or upon the happening of a future occurrence, in which case the determination of the amount of securities into which such security or instrument would be convertible or exercisable shall be made assuming that such security or instrument is immediately convertible or exercisable at the time of such determination; and, *provided*, *further*, that any Proposing Person satisfying the requirements of Rule l3d-1(b)(1) under the Exchange Act (other than a Proposing Person that so satisfies Rule l3d-1(b)(1) under the Exchange Act solely by reason of Rule l3d-1(b)(1) (ii)(E)) shall not be deemed to hold or maintain the notional amount of any securities that underlie a Synthetic Equity Position held by such Proposing Person as a hedge with respect to a bona fide derivatives trade or position of such Proposing Person arising in the ordinary course of such Proposing Person's business as a derivatives dealer, (B) any rights to dividends on the shares of any class or series of shares of the Corporation owned beneficially by such Proposing Person that are separated or separable from the underlying shares of the Corporation, (C)(x) if such Proposing Person is (i) a general or limited partnership, syndicate or other group, the identity of each general partner and each person who functions as a general partner of the general or limited partnership, each member of the syndicate or group and each person controlling the general partner or member, (ii) a corporation or a limited liability company, the identity of each officer and each person who functions as an officer of the corporation or limited liability company, each person controlling the corporation or limited liability company and each officer, director, general partner and person who functions as an officer, director or general partner of any entity ultimately in control of the corporation or limited liability company or (iii) a trust, any trustee of such trust (each such person or persons set forth in the preceding clauses (i), (ii) and (iii), a "Responsible Person"), any fiduciary duties owed by such Responsible Person to the equity holders or other beneficiaries of such Proposing Person and any material interests or relationships of such Responsible Person that are not shared generally by other record or beneficial holders of the shares of any class or series of the Corporation and that reasonably could have influenced the decision of such Proposing Person to propose such business to be brought before the meeting, and (y) if such Proposing Person is a natural person, any material interests or relationships of such natural person that are not shared generally by other record or beneficial holders of the shares of any class or series of the Corporation and that reasonably could have influenced the decision of such Proposing Person to propose such business to be brought before the meeting, (D) any material shares or any Synthetic Equity Position in any principal competitor of the Corporation in any principal industry of the Corporation held by such Proposing Persons, (E) a summary of any material discussions regarding the business proposed to be brought before the meeting (x) between or among any of the Proposing Persons or (y) between or among any Proposing Person and any other record or beneficial holder of the shares of any class or series of the Corporation (including their names), (F) any material pending or threatened legal proceeding in which such Proposing Person is a party or material participant involving the Corporation or any of its officers or directors, or any affiliate of the Corporation, (G) any other material relationship between such Proposing Person, on the one hand, and the Corporation, any affiliate of the Corporation or any principal competitor of the Corporation, on the other hand, (H) any direct or indirect material interest in any material contract or agreement of such Proposing Person with the Corporation, any affiliate of the Corporation or any principal competitor of the Corporation (including, in any such case, any employment agreement, collective bargaining agreement or consulting agreement) and (I) any other information relating to such Proposing Person that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies or consents by such Proposing Person in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act (the disclosures to be made pursuant to the foregoing clauses (A) through (I) are referred to as "Disclosable Interests"); *provided*, *however*, that Disclosable Interests shall not include any such disclosures with respect to the ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner; and

(c) As to each item of business that the stockholder proposes to bring before the annual meeting, (A) a brief description of the business desired to be brought before the annual meeting, the reasons for conducting such business at the annual meeting and any material interest in such business of each Proposing Person, (B) the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend the bylaws of the Corporation, the language of the proposed amendment), (C) a reasonably detailed description of all agreements, arrangements and understandings between or among any of the Proposing Persons or between or among any Proposing Person and any other person or entity (including their names) in connection with the proposal of such business by such stockholder and (D) any other information relating to such item of business that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act; *provided*, *however*, that the disclosures required by this Section 2.4(iii) shall not include any disclosures with respect to any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner.

(iv) For purposes of this Section 2.4, the term "Proposing Person" shall mean (a) the stockholder providing the notice of business proposed to be brought before an annual meeting, (b) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the business proposed to be brought before the annual meeting is made and (c) any participant (as defined in paragraphs (a)(ii)-(vi) of Instruction 3 to Item 4 of Schedule 14A) with such stockholder in such solicitation or associate (within the meaning of Rule 12b-2 under the Exchange Act for the purposes of these bylaws) of such stockholder or beneficial owner.

(v) A Proposing Person shall update and supplement its notice to the Corporation of its intent to propose business at an annual meeting, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 2.4 shall be true and correct as of the record date for notice of the meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the Secretary at the principal executive offices of the Corporation not later than five (5) business days after the record date for notice of the meeting (in the case of the update and supplement required to be made as of such record date), and not later than eight (8) business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof).

(vi) Notwithstanding anything in these bylaws to the contrary, no business shall be conducted at an annual meeting that is not properly brought before the meeting in accordance with this Section 2.4. The presiding officer of the meeting shall, if the facts warrant, determine that the business was not properly brought before the meeting in accordance with this Section 2.4, and if he or she should so determine, he or she shall so declare to the meeting and any such business not properly brought before the meeting shall not be transacted.

(vii) This Section 2.4 is expressly intended to apply to any business proposed to be brought before an annual meeting of stockholders, other than any proposal made in accordance with Rule 14a-8 under the Exchange Act and included in the Corporation's proxy statement. In addition to the requirements of this Section 2.4 with respect to any business proposed to be brought before an annual meeting, each Proposing Person shall comply with all applicable requirements of the Exchange Act with respect to any such business. Nothing in this Section 2.4 shall be deemed to affect the rights of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule l4a-8 under the Exchange Act.

(viii) For purposes of these bylaws, "public disclosure" shall mean disclosure in a press release reported by a national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Sections 13, 14 or 15(d) of the Exchange Act.

2.5 ADVANCE NOTICE PROCEDURES FOR NOMINATIONS OF DIRECTORS.

(i) Nominations of any person for election to the Board at an annual meeting or at a special meeting (but only if the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling such special meeting) may be made at such meeting only (a) by or at the direction of the Board, including by

any committee or persons authorized to do so by the Board or these bylaws, or (b) by a stockholder present in person (A) who was a beneficial owner of shares of the Corporation both at the time of giving the notice provided for in this Section 2.5 and at the time of the meeting, (B) is entitled to vote at the meeting and (C) has complied with this Section 2.5 as to such notice and nomination. The foregoing clause (b) shall be the exclusive means for a stockholder to make any nomination of a person or persons for election to the Board at an annual meeting or special meeting. For purposes of this Section 2.5, "present in person" shall mean that the stockholder proposing that the business be brought before the meeting of the Corporation, or, if the proposing stockholder is not an individual, a qualified representative of such stockholder, appear at such meeting. A "qualified representative" of such proposing stockholder shall be, if such proposing stockholder is (x) a general or limited partnership, any general partner or person who functions as a general partner of the general or limited partnership or who controls the general or limited partnership, (y) a corporation or a limited liability company, any officer or person who functions as an officer of the corporation or limited liability company or any officer, director, general partner or person who functions as an officer, director or general partner of any entity ultimately in control of the corporation or limited liability company or (z) a trust, any trustee of such trust.

(ii) Without qualification, for a stockholder to make any nomination of a person or persons for election to the Board at an annual meeting, the stockholder must (a) provide Timely Notice (as defined in Section 2.4(ii) of these bylaws) thereof in writing and in proper form to the Secretary of the Corporation, (b) provide the information with respect to such stockholder and its proposed nominee as required by this Section 2.5, and (c) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.5. Without qualification, if the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling such special meeting, then for a stockholder to make any nomination of a person or persons for election to the Board at a special meeting, the stockholder must (a) provide timely notice thereof in writing and in proper form to the Secretary of the Corporation at the principal executive offices of the Corporation, (b) provide the information with respect to such stockholder and its proposed nominee as required by this Section 2.5, and (c) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.5. To be timely, a stockholder's notice for nominations to be made at a special meeting must be delivered to, or mailed and received at, the principal executive offices of the Corporation not earlier than the one hundred twentieth (120th) day prior to such special meeting and not later than the ninetieth (90th) day prior to such special meeting or, if later, the tenth (10th) day following the day on which public disclosure (as defined in Section 2.4(ix) of these bylaws) of the date of such special meeting was first made. In no event shall any adjournment or postponement of an annual meeting or special meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice as described above.

(iii) To be in proper form for purposes of this Section 2.5, a stockholder's notice to the Secretary shall set forth:

(a) As to each Nominating Person (as defined below), the Stockholder Information (as defined in Section 2.4(iii)(a) of these bylaws) except that for purposes of this Section 2.5, the term "Nominating Person" shall be substituted for the term "Proposing Person" in all places it appears in Section 2.4(iii)(a);

(b) As to each Nominating Person, any Disclosable Interests (as defined in Section 2.4(iii)(b), except that for purposes of this Section 2.5 the term "Nominating Person" shall be substituted for the term "Proposing Person" in all places it appears in Section 2.4(iii)(b) and the disclosure with respect to the business to be brought before the meeting in Section 2.4(iii)(b) shall be made with respect to the election of directors at the meeting);

(c) As to each person whom a Nominating Person proposes to nominate for election as a director, (A) all information with respect to such proposed nominee that would be required to be set forth in a stockholder's notice pursuant to this Section 2.5 if such proposed nominee were a Nominating Person, (B) all information relating to such proposed nominee that is required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of directors in a contested election pursuant to Section 14(a) under the Exchange Act (including such proposed nominee's written consent to being named in the proxy statement as a nominee and to serving as a director if elected), (C) a description of any direct or indirect material interest in any material contract or agreement between or among any Nominating Person, on the one hand, and each proposed nominee or his or her respective associates or any other participants in such solicitation, on the other hand, including, without limitation, all information that would be required to be disclosed pursuant to Item 404 under Regulation S-K if such Nominating Person were the "registrant" for purposes of such rule and the proposed nominee were a director or executive officer of such registrant (the disclosures to be made pursuant to the foregoing clauses (A) through (C) are referred to as "Nominee Information"), and (D) a completed and signed questionnaire, representation and agreement as provided in Section 2.5(vi); and

(d) The Corporation may require any proposed nominee to furnish such other information (A) as may reasonably be required by the Corporation to determine the eligibility of such proposed nominee to serve as an independent director of the Corporation in accordance with the Corporation's Corporate Governance Guidelines or (B) that could be material to a reasonable stockholder's understanding of the independence or lack of independence of such proposed nominee.

(iv) For purposes of this Section 2.5, the term "Nominating Person" shall mean (a) the stockholder providing the notice of the nomination proposed to be made at the meeting, (b) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the nomination proposed to be made at the meeting is made and (c) any associate of such stockholder or beneficial owner or any other participant in such solicitation.

(v) A stockholder providing notice of any nomination proposed to be made at a meeting shall further update and supplement such notice, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 2.5 shall be true and correct as of the record date for notice of the meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the Secretary at the principal executive offices of the Corporation not later than five (5) business days after the record date for notice of the meeting (in the case of the update and supplement required to be made as of such record date), and not later than eight (8) business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as often (10) business days prior to the meeting or any adjournment or postponement thereof).

(vi) To be eligible to be a nominee for election as a director of the Corporation at an annual or special meeting, the proposed nominee must be nominated in the manner prescribed in Section 2.5 and must deliver (in accordance with the time period prescribed for delivery in a notice to such proposed nominee given by or on behalf of the Board), to the Secretary at the principal executive offices of the Corporation, (a) a completed written questionnaire (in a form provided by the Corporation) with respect to the background, qualifications, stock ownership and independence of such proposed nominee and (b) a written representation and agreement (in form provided by the Corporation) that such proposed nominee (A) is not and, if elected as a director during his or her term of office, will not become a party to (1) any agreement, arrangement or understanding with, and has not given and will not give any commitment or assurance to, any person or entity as to how such proposed nominee, if elected as a director of the Corporation, will act or vote on any issue or question (a "Voting Commitment") or (2) any Voting Commitment that could limit or interfere with such proposed nominee's ability to comply, if elected as a director of the Corporation, with such proposed nominee's fiduciary duties under applicable law, (B) is not, and will not become a party to, any agreement, arrangement or understanding with any person or entity other than the Corporation with respect to any direct or indirect compensation or reimbursement for service as a director and (C) if elected as a director of the Corporation, will comply with all applicable corporate governance, conflict of interest, confidentiality, stock ownership and trading and other policies and guidelines of the Corporation applicable to directors and in effect during such person's term in office as a director (and, if requested by any proposed nominee, the Secretary of the Corporation shall provide to such proposed nominee all such policies and guidelines then in effect).

(vii) In addition to the requirements of this Section 2.5 with respect to any nomination proposed to be made at a meeting, each Proposing Person shall comply with all applicable requirements of the Exchange Act with respect to any such nominations.

(viii) No proposed nominee shall be eligible for nomination as a director of the Corporation unless such proposed nominee and the Nominating Person seeking to place such proposed nominee's name in nomination have complied with this Section 2.5, as applicable. The presiding officer at the meeting shall, if the facts warrant, determine that a nomination was not properly made in accordance with this Section 2.5, and if he or she should so determine, he or she shall so declare such determination to the meeting, the defective nomination shall be disregarded and any ballots cast for the proposed nominee in question (but in the case of any form of ballot listing other qualified nominees, only the ballots case for the nominee in question) shall be void and of no force or effect.

2.6 NOTICE OF STOCKHOLDERS' MEETINGS.

Unless otherwise provided by law, the certificate of incorporation or these bylaws, the notice of any meeting of stockholders shall be sent or otherwise given in accordance with either Section 2.7 or Section 8.1 of these bylaws not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting. The notice shall specify the place, if any, date and hour of the meeting, the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called.

2.7 MANNER OF GIVING NOTICE; AFFIDAVIT OF NOTICE.

Notice of any meeting of stockholders shall be deemed given:

(i) if mailed, when deposited in the U.S. mail, postage prepaid, directed to the stockholder at his or her address as it appears on the Corporation's records; or

(ii) if electronically transmitted as provided in Section 8.1 of these bylaws.

An affidavit of the secretary or an assistant secretary of the Corporation or of the transfer agent or any other agent of the Corporation that the notice has been given by mail or by a form of electronic transmission, as applicable, shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

2.8 QUORUM.

Unless otherwise provided by law, the certificate of incorporation or these bylaws, the holders of a majority in voting power of the stock issued and outstanding and entitled to vote, present in person, or by remote communication, if applicable, or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders. If, however, a quorum is not present or represented at any meeting of the stockholders, then either (i) the chairperson of the meeting or (ii) a majority in voting power of the stockholders entitled to vote at the meeting, present in person, or by remote communication, if applicable, or represented by proxy, shall have power to adjourn the meeting from time to time in the manner provided in Section 2.9 of these bylaws until a quorum is present or represented. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

2.9 ADJOURNED MEETING; NOTICE.

When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

2.10 CONDUCT OF BUSINESS.

The chairperson of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including such regulation of the manner of voting and the conduct of business.

2.11 VOTING.

The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.13 of these bylaws, subject to Section 217 (relating to voting rights of fiduciaries, pledgors and joint owners of stock) and Section 218 (relating to voting trusts and other voting agreements) of the DGCL.

Except as may be otherwise provided in the certificate of incorporation or these bylaws, each stockholder shall be entitled to one (1) vote for each share of capital stock held by such stockholder.

At all duly called or convened meetings of stockholders, at which a quorum is present, for the election of directors, a plurality of the votes cast shall be sufficient to elect a director. Except as otherwise provided by the certificate of incorporation, these bylaws, the rules or regulations of any stock exchange applicable to the Corporation, or applicable law or pursuant to any regulation applicable to the Corporation or its securities, all other elections and questions presented to the stockholders at a duly called or convened meeting, at which a quorum is present, shall be decided by the majority of the votes cast affirmatively or negatively (excluding abstentions and broker non-votes) and shall be valid and binding upon the Corporation.

2.12 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING.

Subject to the rights of the holders of the shares of any series of Preferred Stock or any other class of stock or series thereof having a preference over the Common Stock as to dividends or upon liquidation, any action required or permitted to be taken by the stockholders of the Corporation must be effected at a duly called annual or special meeting of stockholders of the Corporation and may not be effected by any consent in writing by such stockholders.

2.13 RECORD DATE FOR STOCKHOLDER NOTICE; VOTING; GIVING CONSENTS.

In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix, in advance, a record date, which record date shall not precede the date on which the resolution fixing the record date is adopted and which shall not be more than sixty (60) nor less than ten (10) days before the date of such meeting, nor more than sixty (60) days prior to any other such

action.

If the Board does not so fix a record date:

(i) The record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held.

(ii) The record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting;*provided*, *however*, that the Board may fix a new record date for the adjourned meeting.

2.14 PROXIES.

Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy authorized by an instrument in writing or by a transmission permitted by law filed in accordance with the procedure established for the meeting, but no such proxy shall be voted or acted upon after three (3) years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL. A proxy may be in the form of a telegram, cablegram or other means of electronic transmission which sets forth or is submitted with information from which it can be determined that the telegram, cablegram or other means of electronic transmission was authorized by the stockholder.

2.15 LIST OF STOCKHOLDERS ENTITLED TO VOTE.

The officer who has charge of the stock ledger of the Corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The Corporation shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting: (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the Corporation's principal executive office. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting. Such list shall presumptively determine the identity of the stockholders entitled to vote at the meeting and the number of shares held by each of them.

2.16 INSPECTORS OF ELECTION.

Before any meeting of stockholders, the Board shall appoint an inspector or inspectors of election to act at the meeting or its adjournment and make a written report thereof. The number of inspectors shall be either one (1) or three (3). If any person appointed as inspector fails to appear or fails or refuses to act, then the chairperson of the meeting may, and upon the request of any stockholder or a stockholder's proxy shall, appoint a person to fill that vacancy.

Such inspectors shall:

(i) determine the number of shares outstanding and the voting power of each, the number of shares represented at the meeting, the existence of a quorum, and the authenticity, validity, and effect of proxies;

(ii) receive votes or ballots;

(iii) hear and determine all challenges and questions in any way arising in connection with the right to vote;

(iv) count and tabulate all votes;

(v) determine when the polls shall close;

(vi) determine the result; and

(vii) do any other acts that may be proper to conduct the election or vote with fairness to all stockholders.

The inspectors of election shall perform their duties impartially, in good faith, to the best of their ability and as expeditiously as is practical. If there are three (3) inspectors of election, the decision, act or certificate of a majority is effective in all respects as the decision, act or certificate of all. Any report or certificate made by the inspectors of election is prima facie evidence of the facts stated therein.

ARTICLE III - DIRECTORS

3.1 POWERS.

Subject to the provisions of the DGCL and any limitations in the certificate of incorporation or these bylaws relating to action required to be approved by the stockholders or by the outstanding shares, the business and affairs of the Corporation shall be managed and all corporate powers shall be exercised by or under the direction of the Board.

3.2 NUMBER OF DIRECTORS.

The authorized number of directors shall be determined from time to time by resolution of the Board, provided the Board shall consist of at least one (1) member. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

3.3 ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS.

Except as provided in Section 3.4 of these bylaws, each director, including a director elected to fill a vacancy, shall hold office until the expiration of the term for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation or removal. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws. The certificate of incorporation or these bylaws may prescribe other qualifications for directors.

If so provided in the certificate of incorporation, the directors of the Corporation shall be divided into three (3) classes.

3.4 RESIGNATION AND VACANCIES.

Any director may resign at any time upon notice given in writing or by electronic transmission to the Corporation. When one or more directors so resigns and the resignation is effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this section in the filling of other vacancies.

Unless otherwise provided in the certificate of incorporation or these bylaws, vacancies and newly created directorships resulting from any increase in the authorized number of directors shall, unless the Board determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled only by a majority of the directors then in office, although less than a quorum, or by a sole remaining director. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified. A vacancy in the Board shall be deemed to exist under these bylaws in the case of the death, removal or resignation of any director.

3.5 PLACE OF MEETINGS; MEETINGS BY TELEPHONE.

The Board may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the Board, or any committee designated by the Board, may participate in a meeting of the Board, or any committee, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting pursuant to this bylaw shall constitute presence in person at the meeting.

3.6 REGULAR MEETINGS.

Regular meetings of the Board may be held without notice at such time and at such place as shall from time to time be determined by the Board.

3.7 SPECIAL MEETINGS; NOTICE.

Special meetings of the Board for any purpose or purposes may be called at any time by the Board, the chief executive officer, the president, the secretary or a majority of the authorized number of directors. Notice of the time and place of special meetings shall be:

(i) delivered personally by hand, by courier or by telephone;

(ii) sent by United States first-class mail, postage prepaid;

(iii) sent by facsimile; or

(iv) sent by electronic mail,

directed to each director at that director's address, telephone number, facsimile number or electronic mail address, as the case may be, as shown on the Corporation's records.

If the notice is (i) delivered personally by hand, by courier or by telephone, (ii) sent by facsimile or (iii) sent by electronic mail, it shall be delivered or sent at least twenty-four (24) hours before the time of the holding of the meeting. If the notice is sent by U.S. mail, it shall be deposited in the U.S. mail at least four (4) days before the time of the holding of the meeting. Any oral notice may be communicated to the director. The notice need not specify the place of the meeting (if the meeting is to be held at the Corporation's principal executive office) nor the purpose of the meeting.

3.8 QUORUM.

At all meetings of the Board, a majority of the authorized number of directors shall constitute a quorum for the transaction of business. The vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the Board, except as may be otherwise specifically provided by statute, the certificate of incorporation or these bylaws. If a quorum is not present at any meeting of the Board, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

A meeting at which a quorum is initially present may continue to transact business notwithstanding the withdrawal of directors, if any action taken is approved by at least a majority of the required quorum for that meeting.

3.9 BOARD ACTION BY WRITTEN CONSENT WITHOUT A MEETING.

Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting if all members of the Board or committee, as the case may be, consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

3.10 FEES AND COMPENSATION OF DIRECTORS.

Unless otherwise restricted by the certificate of incorporation or these bylaws, the Board shall have the authority to fix the compensation of directors.

3.11 REMOVAL OF DIRECTORS.

Except as otherwise provided by the DGCL, the Board of Directors or any individual director may be removed from office only for cause at a meeting of stockholders called for that purpose, by the affirmative vote of the holders of at least sixty six and two thirds percent (66-2/3%) of the voting power of all the then outstanding shares of

voting stock of the Corporation entitled to vote at an election of directors, voting together as a single class.

No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director's term of office.

ARTICLE IV - COMMITTEES

4.1 COMMITTEES OF DIRECTORS.

The Board may designate one (1) or more committees, each committee to consist of one (1) or more of the directors of the Corporation. The Board may designate one (1) or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board or in these bylaws, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority to (i) approve or adopt, or recommend to the stockholders, any action or matter expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopt, amend or repeal any bylaw of the Corporation.

4.2 COMMITTEE MINUTES.

Each committee shall keep regular minutes of its meetings and report the same to the Board when required.

4.3 MEETINGS AND ACTION OF COMMITTEES.

Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of:

(i) Section 3.5 (place of meetings and meetings by telephone);

(ii) Section 3.6 (regular meetings);

(iii) Section 3.7 (special meetings and notice);

(iv) Section 3.8 (quorum);

(v) Section 7.12 (waiver of notice); and

(vi) Section 3.9 (action without a meeting),

with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the Board and its members*However*:

(i) the time of regular meetings of committees may be determined either by resolution of the Board or by resolution of the committee;

(ii) special meetings of committees may also be called by resolution of the Board; and

(iii) notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The Board may adopt rules for the government of any committee not inconsistent with the provisions of these bylaws.

ARTICLE V - OFFICERS

5.1 OFFICERS.

The officers of the Corporation shall be a president and a secretary. The Corporation may also have, at the discretion of the Board, a chairperson of the Board, a vice chairperson of the Board, a chief executive officer, a chief financial officer or treasurer, one (1) or more vice presidents, one (1) or more assistant vice presidents, one (1) or more assistant treasurers, one (1) or more assistant secretaries, and any such other officers as may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person.

5.2 APPOINTMENT OF OFFICERS.

The Board shall appoint the officers of the Corporation, except such officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws, subject to the rights, if any, of an officer under any contract of employment.

5.3 SUBORDINATE OFFICERS.

The Board may appoint, or empower the chief executive officer or, in the absence of a chief executive officer, the president, to appoint, such other officers and agents as the business of the Corporation may require. Each of such officers and agents shall hold office for such period, have such authority, and perform such duties as are provided in these bylaws or as the Board may from time to time determine.

5.4 REMOVAL AND RESIGNATION OF OFFICERS.

Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by an affirmative vote of the majority of the Board at any regular or special meeting of the Board or, except in the case of an officer chosen by the Board, by any officer upon whom such power of removal may be conferred by the Board.

Any officer may resign at any time by giving written notice to the Corporation. Any resignation shall take effect at the date of the receipt of that notice or at any later time

specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the Corporation under any contract to which the officer is a party.

5.5 VACANCIES IN OFFICES.

Any vacancy occurring in any office of the Corporation shall be filled by the Board or as provided in Section 5.2.

5.6 REPRESENTATION OF SHARES OF OTHER CORPORATIONS.

The chairperson of the Board, the president, any vice president, the treasurer, the secretary or assistant secretary of the Corporation, or any other person authorized by the Board or the president or a vice president, is authorized to vote, represent and exercise on behalf of the Corporation all rights incident to any and all shares of any other corporation or corporations standing in the name of the Corporation. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

5.7 AUTHORITY AND DUTIES OF OFFICERS.

All officers of the Corporation shall respectively have such authority and perform such duties in the management of the business of the Corporation as may be designated from time to time by the Board or the stockholders and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board.

ARTICLE VI - RECORDS AND REPORTS

6.1 MAINTENANCE AND INSPECTION OF RECORDS.

The Corporation shall, either at its principal executive office or at such place or places as designated by the Board, keep a record of its stockholders listing their names and addresses and the number and class of shares held by each stockholder, a copy of these bylaws as amended to date, accounting books and other records.

Any stockholder of record, in person or by attorney or other agent, shall, upon written demand under oath stating the purpose thereof, have the right during the usual hours for business to inspect for any proper purpose the Corporation's stock ledger, a list of its stockholders, and its other books and records and to make copies or extracts therefrom. A proper purpose shall mean a purpose reasonably related to such person's interest as a stockholder. In every instance where an attorney or other agent is the person who seeks the right to inspection, the demand under oath shall be accompanied by a power of attorney or such other writing that authorizes the attorney or other agent so to act on behalf of the stockholder. The demand under oath shall be directed to the Corporation at its registered office in Delaware or at its principal executive office.

6.2 INSPECTION BY DIRECTORS.

Any director shall have the right to examine the Corporation's stock ledger, a list of its stockholders, and its other books and records for a purpose reasonably related to his or her position as a director. The Court of Chancery is hereby vested with the exclusive jurisdiction to determine whether a director is entitled to the inspection sought. The Court may summarily order the Corporation to permit the director to inspect any and all books and records, the stock ledger, and the stock list and to make copies or extracts therefrom. The Court may, in its discretion, prescribe any limitations or conditions with reference to the inspection, or award such other and further relief as the Court may deem just and proper.

ARTICLE VII - GENERAL MATTERS

7.1 EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS.

The Board, except as otherwise provided in these bylaws, may authorize any officer or officers, or agent or agents, to enter into any contract or execute any instrument in the name of and on behalf of the Corporation; such authority may be general or confined to specific instances. Unless so authorized or ratified by the Board or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

7.2 STOCK CERTIFICATES; PARTLY PAID SHARES.

The shares of the Corporation shall be represented by certificates or shall be uncertificated. Certificates for the shares of stock, if any, shall be in such form as is consistent with the certificate of incorporation and applicable law. Every holder of stock represented by a certificate shall be entitled to have a certificate signed by, or in the name of the Corporation by the chairperson or vice-chairperson of the Board, or the president or vice-president, and by the treasurer or an assistant treasurer, or the secretary or an assistant secretary of the Corporation representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if he or she were such officer, transfer agent or registrar at the date of issue.

The Corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly paid shares, upon the books and records of the Corporation in the case of uncertificated partly paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully paid shares, the Corporation shall declare a dividend upon partly paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

7.3 SPECIAL DESIGNATION ON CERTIFICATES.

If the Corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock; *provided*, *however*, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements, there may be set forth on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

7.4 LOST CERTIFICATES.

Except as provided in this Section 7.4, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the Corporation and cancelled at the same time. The Corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the Corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the

issuance of such new certificate or uncertificated shares.

7.5 CONSTRUCTION; DEFINITIONS.

Unless the context requires otherwise, the general provisions, rules of construction and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term "person" includes both a corporation and a natural person.

7.6 DIVIDENDS.

The Board, subject to any restrictions contained in either (i) the DGCL or (ii) the certificate of incorporation, may declare and pay dividends upon the shares of its capital stock. Dividends may be paid in cash, in property or in shares of the Corporation's capital stock.

The Board may set apart out of any of the funds of the Corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve. Such purposes shall include but not be limited to equalizing dividends, repairing or maintaining any property of the Corporation, and meeting contingencies.

7.7 FISCAL YEAR

The fiscal year of the Corporation shall be fixed by resolution of the Board and may be changed by the Board.

7.8 SEAL.

The Corporation may adopt a corporate seal, which shall be adopted and which may be altered by the Board. The Corporation may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

7.9 TRANSFER OF STOCK.

Shares of the Corporation shall be transferable in the manner prescribed by law and in these bylaws. Shares of stock of the Corporation shall be transferred on the books of the Corporation only by the holder of record thereof or by such holder's attorney duly authorized in writing, upon surrender to the Corporation of the certificate or certificates representing such shares endorsed by the appropriate person or persons (or by delivery of duly executed instructions with respect to uncertificated shares), with such evidence of the authenticity of such endorsement or execution, transfer, authorization and other matters as the Corporation may reasonably require, and accompanied by all necessary stock transfer stamps. No transfer of stock shall be valid as against the Corporation for any purpose until it shall have been entered in the stock records of the Corporation by an entry showing the names of the persons from and to whom it was transferred.

7.10 STOCK TRANSFER AGREEMENTS.

The Corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the Corporation to restrict the transfer of shares of stock of the Corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

7.11 REGISTERED STOCKHOLDERS.

The Corporation:

(i) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner;

(ii) shall be entitled to hold liable for calls and assessments the person registered on its books as the owner of shares; and

(iii) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

7.12 WAIVER OF NOTICE.

Whenever notice is required to be given under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

ARTICLE VIII - NOTICE BY ELECTRONIC TRANSMISSION

8.1 NOTICE BY ELECTRONIC TRANSMISSION.

Without limiting the manner by which notice otherwise may be given effectively to stockholders pursuant to the DGCL, the certificate of incorporation or these bylaws, any notice to stockholders given by the Corporation under any provision of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice to the Corporation. Any such consent shall be deemed revoked if:

(i) the Corporation is unable to deliver by electronic transmission two (2) consecutive notices given by the Corporation in accordance with such consent; and

(ii) such inability becomes known to the secretary or an assistant secretary of the Corporation or to the transfer agent, or other person responsible for the giving of notice.

However, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action.

Any notice given pursuant to the preceding paragraph shall be deemed given:

(i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice;

(ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice;

(iii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (A) such posting and (B) the giving of such separate notice; and

(iv) if by any other form of electronic transmission, when directed to the stockholder.

An affidavit of the secretary or an assistant secretary or of the transfer agent or other agent of the Corporation that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

8.2 DEFINITION OF ELECTRONIC TRANSMISSION.

An "electronic transmission" means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

ARTICLE IX - INDEMNIFICATION

9.1 INDEMNIFICATION OF DIRECTORS AND OFFICERS.

The Corporation shall indemnify and hold harmless, to the fullest extent permitted by the DGCL as it presently exists or may hereafter be amended, any director or officer of the Corporation who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding") by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was a director or officer of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or non-profit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such person in connection with any such Proceeding. Notwithstanding the preceding sentence, except as otherwise provided in Section 9.4, the Corporation shall be required to indemnify a person in connection with a Proceeding initiated by such person only if the Proceeding was authorized in the specific case by the Board.

9.2 INDEMNIFICATION OF OTHERS.

The Corporation shall have the power to indemnify and hold harmless, to the extent permitted by applicable law as it presently exists or may hereafter be amended, any employee or agent of the Corporation who was or is made or is threatened to be made a party or is otherwise involved in any Proceeding by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was an employee or agent of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or non-profit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses reasonably incurred by such person in connection with any such Proceeding.

9.3 PREPAYMENT OF EXPENSES.

The Corporation shall to the fullest extent not prohibited by applicable law pay the expenses (including attorneys' fees) incurred by any officer or director of the Corporation, and may pay the expenses incurred by any employee or agent of the Corporation, in defending any Proceeding in advance of its final disposition; *provided*, *however*, that, to the extent required by law, such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the person to repay all amounts advanced if it should be ultimately determined that the person is not entitled to be indemnified under this Article IX or otherwise.

9.4 DETERMINATION; CLAIM.

If a claim for indemnification (following the final disposition of such Proceeding) or advancement of expenses under this Article IX is not paid in full within sixty (60) days after a written claim therefor has been received by the Corporation the claimant may file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim to the fullest extent permitted by law. In any such action the Corporation shall have the burden of proving that the claimant was not entitled to the requested indemnification or payment of expenses under applicable law.

9.5 NON-EXCLUSIVITY OF RIGHTS.

The rights conferred on any person by this Article IX shall not be exclusive of any other rights which such person may have or hereafter acquire under any statute, provision of the certificate of incorporation, these bylaws, agreement, vote of stockholders or disinterested directors or otherwise.

9.6 INSURANCE.

The Corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust enterprise or non-profit entity against any liability asserted against him or her and incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify him or her against such liability under the provisions of the DGCL.

9.7 OTHER INDEMNIFICATION.

The Corporation's obligation, if any, to indemnify or advance expenses to any person who was or is serving at its request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust, enterprise or non-profit entity shall be reduced by any amount such person may collect as indemnification or advancement of expenses from such other corporation, partnership, joint venture, trust, enterprise or non-profit enterprise.

9.8 CONTINUATION OF INDEMNIFICATION.

The rights to indemnification and to prepayment of expenses provided by, or granted pursuant to, this Article IX shall continue notwithstanding that the person has ceased to be a director or officer of the Corporation and shall inure to the benefit of the estate, heirs, executors, administrators, legatees and distributees of such person.

9.9 AMENDMENT OR REPEAL.

The provisions of this Article IX shall constitute a contract between the Corporation, on the one hand, and, on the other hand, each individual who serves or has served as a director or officer of the Corporation (whether before or after the adoption of these bylaws), in consideration of such person's performance of such services, and pursuant to this Article IX the Corporation intends to be legally bound to each such current or former director or officer of the Corporation. With respect to current and former directors and officers of the Corporation, the rights conferred under this Article IX are present contractual rights and such rights are fully vested, and shall be deemed to have vested fully, immediately upon adoption of theses bylaws. With respect to any directors or officers of the Corporation who commence service following adoption of these bylaws, the rights conferred under this provision shall be present contractual rights and such rights shall fully vest, and be deemed to have vested fully, immediately upon such director or officer commencing service as a director or officer of the Corporation. Any repeal or modification of the foregoing provisions of this Article IX shall not adversely affect any right or protection (i) hereunder of any person in respect of any act or omission occurring prior to the time of such repeal or modification or (ii) under any agreement providing for indemnification or advancement of expenses to an officer or director of the Corporation in effect prior to the time of such repeal or modification.

ARTICLE X - AMENDMENTS

Subject to the limitations set forth in Section 9.9 of these bylaws or the provisions of the certificate of incorporation, the Board is expressly empowered to adopt, amend or repeal the bylaws of the Corporation. Any adoption, amendment or repeal of the bylaws of the Corporation by the Board shall require the approval of a majority of the authorized number of directors. The stockholders also shall have power to adopt, amend or repeal the bylaws of the Corporation at any annual or special meeting of stockholders, provided that notice of such proposed adoption, amendment or repeal is given in the notice of such meeting of stockholders..

NUMBER
UC

SHARES
SPECIMEN

SEE REVERSE FOR CERTAIN DEFINITIONS

UNICYCIVE THERAPEUTICS INC.

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

COMMON STOCK

THIS CERTIFIES THAT:

SPECIMEN - NOT NEGOTIABLE

IS THE OWNER OF

FULLY PAID AND NON-ASSESSABLE SHARES OF COMMON STOCK OF $0.001 PAR VALUE EACH OF

UNICYCIVE THERAPEUTICS, INC.

transferable on the books of the Corporation in person or by duly authorized attorney upon surrender of this certificate duly endorsed or assigned. This certificate and the shares represented hereby are subject to the laws of the State of Delaware, and to the Certificate of Incorporation and Bylaws of the Corporation, as now or hereafter amended.

This certificate is not valid until countersigned by the Transfer Agent.

WITNESS the facsimile seal of the Corporation and the facsimile signatures of its duly authorized officers.

DATED:

COUNTERSIGNED:
PHILADELPHIA STOCK TRANSFER, INC.
2320 HAVERFORD RD., SUITE 230, ARDMORE, PA 19003
TRANSFER AGENT

BY:

AUTHORIZED SIGNATURE

UNICYCIVE THERAPEUTICS, INC. CORPORATE SEAL 2016 DELAWARE

SPECIMEN
NOT NEGOTIABLE

SECRETARY

PRESIDENT & CEO

© COLUMBIA PRINTING SERVICES, LLC

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM - as tenants in common
TEN ENT - as tenants by the entireties
JT TEN - as joint tenants with right of survivorship and not as tenants in common

UNIF GIFT MIN ACT - .....Custodian.....
(Cust) (Minor)
under Uniform Gifts to Minors Act .....
(State)

Additional abbreviations may also be used though not in the above list.

For Value Received,_____ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

_____

(PLEASE PRINT OR TYPE NAME AND ADDRESS, INCLUDING ZIP CODE, OF ASSIGNEE)

_____

_____

_____ *Shares*
of the stock represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ *Attorney*
to transfer the said stock on the books of the within named Corporation with full power of substitution in the premises.

Dated _____

NOTICE: THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATSOEVER.

Signature(s) Guaranteed

By _____
The Signature(s) must be guaranteed by an eligible guarantor institution (Banks, Stockbrokers, Savings and Loan Associations and Credit Unions with membership in an approved Signature Guarantee Medallion Program), pursuant to SEC Rule 17Ad-15.

THE CORPORATION WILL FURNISH TO ANY STOCKHOLDER, UPON REQUEST AND WITHOUT CHARGE, A FULL STATEMENT OF THE DESIGNATIONS, RELATIVE RIGHTS, PREFERENCES AND LIMITATIONS OF THE SHARES OF EACH CLASS AND SERIES AUTHORIZED TO BE ISSUED, SO FAR AS THE SAME HAVE BEEN DETERMINED, AND OF THE AUTHORITY, IF ANY, OF THE BOARD TO DIVIDE THE SHARES INTO CLASSES OR SERIES AND TO DETERMINE AND CHANGE THE RELATIVE RIGHTS, PREFERENCES AND LIMITATIONS OF ANY CLASS OR SERIES. SUCH REQUEST MAY BE MADE TO THE SECRETARY OF THE CORPORATION OR TO THE TRANSFER AGENT NAMED ON THIS CERTIFICATE.

UNICYCIVE THERAPEUTICS, INC.
2021 OMNIBUS EQUITY INCENTIVE PLAN

Section 1. **Purpose of Plan.**

The name of the Plan is the Unicycive Therapeutics, Inc. 2021 Omnibus Equity Incentive Plan. The purposes of the Plan are to (i) provide an additional incentive to selected employees, directors, independent contractors and consultants of the Company or its Affiliates whose contributions are essential to the growth and success of the Company, (ii) strengthen the commitment of such individuals to the Company and its Affiliates, (iii) motivate those individuals to faithfully and diligently perform their responsibilities and (iv) attract and retain competent and dedicated individuals whose efforts will result in the long-term growth and profitability of the Company. To accomplish these purposes, the Plan provides that the Company may grant Options, Share Appreciation Rights, Restricted Shares, Restricted Stock Units, Other Share-Based Awards, Cash Awards or any combination of the foregoing.

Section 2. **Definitions.**

For purposes of the Plan, the following terms shall be defined as set forth below:

(a) "Administrator" means the Board, or, if and to the extent the Board does not administer the Plan, the Committee in accordance with Section 3 hereof.

(b) "Affiliate" means a Person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the Person specified as of any date of determination.

(c) "Applicable Laws" means the applicable requirements under U.S. federal and state corporate laws, U.S. federal and state securities laws, including the Code, any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws of any other country or jurisdiction where Awards are granted under the Plan, as are in effect from time to time.

(d) "Award" means any Option, Share Appreciation Right, Restricted Share, Restricted Stock Unit, Other Share-Based Award or Cash Award granted under the Plan.

(e) "Award Agreement" means any written notice, agreement, contract or other instrument or document evidencing an Award, including through electronic medium, which shall contain such terms and conditions with respect to an Award as the Administrator shall determine, consistent with the Plan.

(f) "Beneficial Owner" (or any variant thereof) has the meaning defined in Rule 13d-3 under the Exchange Act.

(g) "Board" means the Board of Directors of the Company.

(h) "Bylaws" mean the bylaws of the Company, as may be amended and/or restated from time to time.

(i) "Cash Award" means cash awarded under Section 11 of the Plan, including cash awarded as a bonus or upon the attainment of performance goals or otherwise as permitted under the Plan.

(j) "Cause" has the meaning assigned to such term in any individual service, employment or severance agreement or Award Agreement with the Participant or, if no such agreement exists or if such agreement does not define "Cause," then "Cause" means (i) the conviction, guilty plea or plea of "no contest" by the Participant to any felony or a crime involving moral turpitude or the Participant's commission of any other act or omission involving dishonesty or fraud, (ii) the substantial and repeated failure of the Participant to perform duties of the office held by the Participant, (iii) the Participant's gross negligence, willful misconduct or breach of fiduciary duty with respect to the Company or any of its Subsidiaries or Affiliates, (iv) any breach by the Participant of any restrictive covenants to which the Participant is subject, and/or (v) the Participant's engagement in any conduct which is or can reasonably be expected to be materially detrimental or injurious to the business or reputation of the Company or its Affiliates. Any voluntary termination of employment or service by the Participant in anticipation of an involuntary termination of the Participant's employment or service, as applicable, for Cause shall be deemed to be a termination for Cause.

(k) "Change in Capitalization" means any (i) merger, consolidation, reclassification, recapitalization, spin-off, spin-out, repurchase or other reorganization or corporate transaction or event, (ii) special or extraordinary dividend or other extraordinary distribution (whether in the form of cash, Common Stock or other property), stock split, reverse stock split, share subdivision or consolidation, (iii) combination or exchange of shares or (iv) other change in corporate structure, which, in any such case, the Administrator determines, in its sole discretion, affects the Shares such that an adjustment pursuant to Section 5 hereof is appropriate.

(l) "Change in Control" means the first occurrence of an event set forth in any one of the following paragraphs following the Effective Date:

(1) any Person is or becomes the Beneficial Owner, directly or indirectly, of securities of the Company (not including in the securities Beneficially Owned by such Person which were acquired directly from the Company or any Affiliate thereof) representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities, excluding any Person who becomes such a Beneficial Owner in connection with a transaction described in clause (i) of paragraph (3) below; or

(2) the date on which individuals who constitute the Board as of the Effective Date and any new director (other than a director whose initial assumption of office is in connection with an actual or threatened election contest, including, but not limited to, a consent solicitation, relating to the election of directors of the Company) whose appointment or election by the Board or nomination for election by the Company's stockholders was approved or recommended by a vote of at least two-thirds (2/3) of the directors then still in office who either were directors on the Effective Date or whose appointment, election or nomination for election was previously so approved or recommended cease for any reason to constitute a majority of the number of directors serving on the Board; or

(3) there is consummated a merger or consolidation of the Company or any direct or indirect Subsidiary with any other corporation or other entity, other than (i) a merger or consolidation (A) which results in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof), in combination with the ownership of any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary, fifty percent (50%) or more of the combined voting power of the securities of the Company or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation and (B) following which the individuals who comprise the Board immediately prior thereto constitute at least a majority of the board of directors of the Company, the entity surviving such merger or consolidation or, if the Company or the entity surviving such merger or consolidation is then a Subsidiary, the ultimate parent thereof, or (ii) a merger or consolidation effected to implement a recapitalization of the Company (or similar transaction) in which no Person is or becomes the Beneficial Owner, directly or indirectly, of securities of the Company (not including in the securities Beneficially Owned by such Person any securities acquired directly from the Company or its Affiliates) representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities; or

(4) the stockholders of the Company approve a plan of complete liquidation or dissolution of the Company or there is consummated an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets, other than (A) a sale or disposition by the Company of all or substantially all of the Company's assets to an entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are owned by stockholders of the Company following the completion of such transaction in substantially the same proportions as their ownership of the Company immediately prior to such sale or (B) a sale or disposition of all or substantially all of the Company's assets immediately following which the individuals who comprise the Board immediately prior thereto constitute at least a majority of the board of directors of the entity to which such assets are sold or disposed or, if such entity is a subsidiary, the ultimate parent thereof.

Notwithstanding the foregoing, (i) a Change in Control shall not be deemed to have occurred by virtue of the consummation of any transaction or series of integrated transactions immediately following which the holders of Common Stock immediately prior to such transaction or series of transactions continue to have substantially the same proportionate ownership in an entity which owns all or substantially all of the assets of the Company immediately following such transaction or series of transactions and (ii) to the extent required to avoid accelerated taxation and/or tax penalties under Section 409A of the Code, a Change in Control shall be deemed to have occurred under the Plan with respect to any Award that constitutes deferred compensation under Section 409A of the Code only if a change in the ownership or effective control of the Company or a change in ownership of a substantial portion of the assets of the Company shall also be deemed to have occurred under Section 409A of the Code. For purposes of this definition of Change in Control, the term "Person" shall not include (i) the Company or any Subsidiary thereof, (ii) a trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary thereof, (iii) an underwriter temporarily holding securities pursuant to an offering of such securities, or (iv) a corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of shares of the Company.

(m) "Code" means the Internal Revenue Code of 1986, as amended from time to time, or any successor thereto.

(n) "Committee" means any committee or subcommittee the Board may appoint to administer the Plan. Subject to the discretion of the Board, the Committee shall be composed entirely of individuals who meet the qualifications of a "non-employee director" within the meaning of Rule 16b-3 under the Exchange Act and any other qualifications required by the applicable stock exchange on which the Common Stock is traded.

(o) "Common Stock" means the common stock of the Company, having a par value of $0.001 per share.

(p) "Company" means Unicycive Therapeutics, Inc., a Delaware corporation (or any successor company, except as the term "Company" is used in the definition of "Change in Control" above).

(q) "Disability" has the meaning assigned to such term in any individual service, employment or severance agreement or Award Agreement with the Participant or, if no such agreement exists or if such agreement does not define "Disability," then "Disability" means that a Participant, as determined by the Administrator in its sole discretion, (i) is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months, or (ii) is, by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months, receiving income replacement benefits for a period of not less than three (3) months under an accident and health plan covering employees of the Company or an Affiliate thereof.

(r) "Effective Date" has the meaning set forth in Section 18 hereof.

(s) "Eligible Recipient" means an employee, director, independent contractor or consultant of the Company or any Affiliate of the Company who has been selected as an eligible participant by the Administrator; provided, however, to the extent required to avoid accelerated taxation and/or tax penalties under Section 409A of the Code, an Eligible Recipient of an Option or a Stock Appreciation Right means an employee, non-employee director, independent contractor or consultant of the Company or any Affiliate of the Company with respect to whom the Company is an "eligible issuer of service recipient stock" within the meaning of Section 409A of the Code.

(t) "Exchange Act" means the Securities Exchange Act of 1934, as amended from time to time.

(u) "Exempt Award" shall mean the following:

(1) An Award granted in assumption of, or in substitution for, outstanding awards previously granted by a corporation or other entity acquired by the Company or any of its Subsidiaries or with which the Company or any of its Subsidiaries combines by merger or otherwise. The terms and conditions of any such Awards may vary from the terms and conditions set forth in the Plan to the extent the Administrator at the time of grant may deem appropriate, subject to Applicable Laws.

(2) An "employment inducement" award as described in the applicable stock exchange listing manual or rules may be granted under the Plan from time to time. The terms and conditions of any "employment inducement" award may vary from the terms and conditions set forth in the Plan to such extent as the Administrator at the time of grant may deem appropriate, subject to Applicable Laws.

(3) An award that an Eligible Recipient purchases at Fair Market Value (including awards that an Eligible Recipient elects to receive in lieu of fully vested compensation that is otherwise due) whether or not the Shares are delivered immediately or on a deferred basis.

(v) "Exercise Price" means, (i) with respect to any Option, the per share price at which a holder of such Option may purchase Shares issuable upon exercise of such Award, and (ii) with respect to a Share Appreciation Right, the base price per share of such Share Appreciation Right.

(w) "Fair Market Value" of a share of Common Stock or another security as of a particular date shall mean the fair market value as determined by the Administrator in its sole discretion; provided, that, (i) if the Common Stock or other security is admitted to trading on a national securities exchange, the fair market value on any date shall be the closing sale price reported on such date, or if no shares were traded on such date, on the last preceding date for which there was a sale of a share of Common Stock on such exchange, or (ii) if the Common Stock or other security is then traded in an over-the-counter market, the fair market value on any date shall be the average of the closing bid and asked prices for such share in such over-the-counter market for the last preceding date on which there was a sale of such share in such market.

(x) "Free Standing Rights" has the meaning set forth in Section 8.

(y) "Good Reason" has the meaning assigned to such term in any individual service, employment or severance agreement or Award Agreement with the Participant or, if no such agreement exists or if such agreement does not define "Good Reason," "Good Reason" and any provision of this Plan that refers to "Good Reason" shall not be applicable to such Participant.

(z) Intentionally omitted.

(aa) "Incentive Compensation" means annual cash bonus and any Award.

(bb) "ISO" means an Option intended to be and designated as an "incentive stock option" within the meaning of Section 422 of the Code.

(cc) "Nonqualified Stock Option" shall mean an Option that is not designated as an ISO.

(dd) "Option" means an option to purchase shares of Common Stock granted pursuant to Section 7 hereof. The term "Option" as used in the Plan includes the terms "Nonqualified Stock Option" and "ISO."

(ee) "Other Share-Based Award" means a right or other interest granted pursuant to Section 10 hereof that may be denominated or payable in, valued in whole or in part by reference to, or otherwise based on or related to, Common Stock, including, but not limited to, unrestricted Shares, dividend equivalents or performance units, each of which may be subject to the attainment of performance goals or a period of continued provision of service or employment or other terms or conditions as permitted under the Plan.

(ff) "Participant" means any Eligible Recipient selected by the Administrator, pursuant to the Administrator's authority provided for in Section 3 below, to receive grants of Awards, and, upon his or her death, his or her successors, heirs, executors and administrators, as the case may be.

(gg) "Person" shall have the meaning given in Section 3(a)(9) of the Exchange Act, as modified and used in Sections 13(d) and 14(d) thereof.

(hh) "Plan" means this 2020 Omnibus Equity Incentive Plan.

(ii) "Related Rights" has the meaning set forth in Section 8.

(jj) "Restricted Share" means a Share granted pursuant to Section 9 below subject to certain restrictions that lapse at the end of a specified period (or periods) of time and/or upon attainment of specified performance objectives.

(kk) "Restricted Period" has the meaning set forth in Section 9.

(ll) "Restricted Stock Unit" means the right granted pursuant to Section 9 hereof to receive a Share at the end of a specified restricted period (or periods) of time and/or upon attainment of specified performance objectives.

(mm) "Rule 16b-3" has the meaning set forth in Section 3.

(nn) "Section 16 Officer" means any officer of the Company whom the Board has determined is subject to the reporting requirements of Section 16 of the Exchange Act, whether or not such individual is a Section 16 Officer at the time the determination to recoup compensation is made.

(oo) "Shares" means Common Stock reserved for issuance under the Plan, as adjusted pursuant to the Plan, and any successor (pursuant to a merger, consolidation or other reorganization) security.

(pp) "Share Appreciation Right" means a right granted pursuant to Section 8 hereof to receive an amount equal to the excess, if any, of (i) the aggregate Fair Market Value, as of the date such Award or portion thereof is surrendered, of the Shares covered by such Award or such portion thereof, over (ii) the aggregate Exercise Price of such Award or such portion thereof.

(qq) "Subsidiary" means, with respect to any Person, as of any date of determination, any other Person as to which such first Person owns or otherwise controls, directly or indirectly, more than 50% of the voting shares or other similar interests or a sole general partner interest or managing member or similar interest of such other Person.

(rr) "Term" has the meaning set forth in Section 3.

(ss) "Transfer" has the meaning set forth in Section 16.

Section 3. **Administration.**

(a) The Plan shall be administered by the Administrator and shall be administered, to the extent applicable, in accordance with Rule 16b-3 under the Exchange Act ("Rule 16b-3").

(b) Pursuant to the terms of the Plan, the Administrator, subject, in the case of any Committee, to any restrictions on the authority delegated to it by the Board, shall have the power and authority, without limitation:

(1) to select those Eligible Recipients who shall be Participants;

(2) to determine whether and to what extent Options, Share Appreciation Rights, Restricted Shares, Restricted Stock Units, Cash Awards, Other Share-Based Awards or a combination of any of the foregoing, are to be granted hereunder to Participants;

(3) to determine the number of Shares to be covered by each Award granted hereunder;

(4) to determine the terms and conditions, not inconsistent with the terms of the Plan, of each Award granted hereunder (including, but not limited to, (i) the restrictions applicable to Restricted Shares or Restricted Stock Units and the conditions under which restrictions applicable to such Restricted Shares or Restricted Stock Units shall lapse, (ii) the performance goals and periods applicable to Awards, (iii) the Exercise Price of each Option and each Share Appreciation Right or the purchase price of any other Award, (iv) the vesting schedule and terms applicable to each Award, (v) the number of Shares or amount of cash or other property subject to each Award and (vi) subject to the requirements of Section 409A of the Code (to the extent applicable) and to Section 4(e) of the Plan, any amendments to the terms and conditions of

outstanding Awards, including, but not limited to, extending the exercise period of such Awards and accelerating the vesting and/or payment schedules of such Awards);

(5) to determine the terms and conditions, not inconsistent with the terms of the Plan, which shall govern all written instruments evidencing Awards;

(6) to determine the Fair Market Value in accordance with the terms of the Plan;

(7) to determine the duration and purpose of leaves of absence which may be granted to a Participant without constituting termination of the Participant's service or employment for purposes of Awards granted under the Plan;

(8) to adopt, alter and repeal such administrative rules, regulations, guidelines and practices governing the Plan as it shall from time to time deem advisable;

(9) to construe and interpret the terms and provisions of, and supply or correct omissions in, the Plan and any Award issued under the Plan (and any Award Agreement relating thereto), and to otherwise supervise the administration of the Plan and to exercise all powers and authorities either specifically granted under the Plan or necessary and advisable in the administration of the Plan; and

(10) to prescribe, amend and rescind rules and regulations relating to sub-plans established for the purpose of satisfying applicable non-United States laws or for qualifying for favorable tax treatment under applicable non-United States laws, which rules and regulations may be set forth in an appendix or appendixes to the Plan.

(c) Subject to Section 5, neither the Board nor the Committee shall have the authority to reprice or cancel and regrant any Award at a lower exercise, base or purchase price or cancel any Award with an exercise, base or purchase price in exchange for cash, property or other Awards without first obtaining the approval of the Company's shareholders.

(d) All decisions made by the Administrator pursuant to the provisions of the Plan shall be final, conclusive and binding on all Persons, including the Company and the Participants.

(e) The expenses of administering the Plan shall be borne by the Company and its Affiliates.

(f) If at any time or to any extent the Board shall not administer the Plan, then the functions of the Administrator specified in the Plan shall be exercised by the Committee. Except as otherwise provided in the Certificate of Incorporation or Bylaws of the Company, any action of the Committee with respect to the administration of the Plan shall be taken by a majority vote at a meeting at which a quorum is duly constituted or unanimous written consent of the Committee's members.

Section 4. **Shares Reserved for Issuance Under the Plan.**

(a) Subject to Section 5 hereof, the number of shares of Common Stock that are reserved and available for issuance pursuant to Awards granted under the Plan shall be equal to 5,600,000 shares of Common Stock; provided, that, shares of Common Stock issued under the Plan with respect to an Exempt Award shall not count against such share limit.

(b) Shares issued under the Plan may, in whole or in part, be authorized but unissued Shares or Shares that shall have been or may be reacquired by the Company in the open market, in private transactions or otherwise. If an Award entitles the Participant to receive or purchase Shares, the number of Shares covered by such Award or to which such Award relates shall be counted on the date of grant of such Award against the aggregate number of Shares available for granting Awards under the Plan. If any Shares subject to an Award are forfeited, cancelled, exchanged or surrendered or if an Award otherwise terminates or expires without a distribution of shares to the Participant, the Shares with respect to such Award shall, to the extent of any such forfeiture, cancellation, exchange, surrender, termination or expiration, again be available for granting Awards under the Plan. Notwithstanding the foregoing, Shares surrendered or withheld as payment of either the Exercise Price of an Award (including Shares otherwise underlying a Share Appreciation Right that are retained by the Company to account for the Exercise Price of such Share Appreciation Right) and/or withholding taxes in respect of an Award shall no longer be available for grant under the Plan. In addition, (i) to the extent an Award is denominated in shares of Common Stock, but paid or settled in cash, the number of shares of Common Stock with respect to which such payment or settlement is made shall again be available for grants of Awards pursuant to the Plan and (ii) shares of Common Stock underlying Awards that can only be settled in cash shall not be counted against the aggregate number of shares of Common Stock available for Awards under the Plan. Upon the exercise of any Award granted in tandem with any other Awards, such related Awards shall be cancelled to the extent of the number of Shares as to which the Award is exercised and, notwithstanding the foregoing, such number of shares shall no longer be available for grant under the Plan.

(c) No more than 5,600,000 Shares shall be issued pursuant to the exercise of ISOs.

(d) No Participant who is a non-employee director of the Company shall be granted Awards during any calendar year that, when aggregated with such non-employee director's cash fees with respect to such calendar year, exceed $500,000 in total value (with Cash Awards or other cash fees measured for this purpose at their value upon payment and any other Awards measured for this purpose at their grant date fair value as determined for the Company's financial reporting purposes).

(e) Notwithstanding anything to the contrary in the Plan except for Section 12 of the Plan, any Awards granted under the Plan (other than such Awards representing a maximum of five percent (5%) of the Shares reserved for issuance under the Plan pursuant to Section 4(a) hereof) shall be granted subject to a minimum vesting period of at least twelve (12) months.

Section 5. **Equitable Adjustments.**

In the event of any Change in Capitalization, an equitable substitution or proportionate adjustment shall be made in (i) the aggregate number and kind of securities reserved for issuance under the Plan pursuant to Section 4, (ii) the kind, number of securities subject to, and the Exercise Price subject to outstanding Options and Share Appreciation Rights granted under the Plan, (iii) the kind, number and purchase price of Shares or other securities or the amount of cash or amount or type of other property subject to outstanding Restricted Shares, Restricted Stock Units or Other Share-Based Awards granted under the Plan; and/or (iv) the terms and conditions of any outstanding Awards (including, without limitation, any applicable performance targets or criteria with respect thereto); provided, however, that any fractional shares resulting from the adjustment shall be eliminated. Such other equitable substitutions or adjustments shall be made as may be determined by the Administrator, in its sole discretion. Without limiting the generality of the foregoing, in connection with a Change in Capitalization, the Administrator may provide, in its sole discretion, but subject in all events to the requirements of Section 409A of the Code, for the cancellation of any outstanding Award granted hereunder in exchange for payment in cash or other property having an aggregate Fair Market Value equal to the Fair Market Value of the Shares, cash or other property covered by such Award, reduced by the aggregate Exercise Price or purchase

price thereof, if any; provided, however, that if the Exercise Price or purchase price of any outstanding Award is equal to or greater than the Fair Market Value of the shares of Common Stock, cash or other property covered by such Award, the Administrator may cancel such Award without the payment of any consideration to the Participant. Further, without limiting the generality of the foregoing, with respect to Awards subject to foreign laws, adjustments made hereunder shall be made in compliance with applicable requirements. Except to the extent determined by the Administrator, any adjustments to ISOs under this Section 5 shall be made only to the extent not constituting a "modification" within the meaning of Section 424(h)(3) of the Code. The Administrator's determinations pursuant to this Section 5 shall be final, binding and conclusive.

Section 6. **Eligibility.**

The Participants in the Plan shall be selected from time to time by the Administrator, in its sole discretion, from those individuals that qualify as Eligible Recipients.

Section 7. **Options.**

(a) General. Options granted under the Plan shall be designated as Nonqualified Stock Options or ISOs. Each Participant who is granted an Option shall enter into an Award Agreement with the Company, containing such terms and conditions as the Administrator shall determine, in its sole discretion, including, among other things, the Exercise Price of the Option, the term of the Option and provisions regarding exercisability of the Option, and whether the Option is intended to be an ISO or a Nonqualified Stock Option (and in the event the Award Agreement has no such designation, the Option shall be a Nonqualified Stock Option). The provisions of each Option need not be the same with respect to each Participant. More than one Option may be granted to the same Participant and be outstanding concurrently hereunder. Options granted under the Plan shall be subject to the terms and conditions set forth in this Section 7 and shall contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Administrator shall deem desirable and set forth in the applicable Award Agreement.

(b) Exercise Price. The Exercise Price of Shares purchasable under an Option shall be determined by the Administrator in its sole discretion at the time of grant, but in no event shall the exercise price of an Option be less than one hundred percent (100%) of the Fair Market Value of a share of Common Stock on the date of grant.

(c) Option Term. The maximum term of each Option shall be fixed by the Administrator, but no Option shall be exercisable more than ten (10) years after the date such Option is granted. Each Option's term is subject to earlier expiration pursuant to the applicable provisions in the Plan and the Award Agreement. Notwithstanding the foregoing, subject to Section 4(e) of the Plan, the Administrator shall have the authority to accelerate the exercisability of any outstanding Option at such time and under such circumstances as the Administrator, in its sole discretion, deems appropriate.

(d) Exercisability. Each Option shall be exercisable at such time or times and subject to such terms and conditions, including the attainment of performance goals, as shall be determined by the Administrator in the applicable Award Agreement. The Administrator may also provide that any Option shall be exercisable only in installments, and the Administrator may waive such installment exercise provisions at any time, in whole or in part, based on such factors as the Administrator may determine in its sole discretion.

(e) Method of Exercise. Options may be exercised in whole or in part by giving written notice of exercise to the Company specifying the number of whole Shares to be purchased, accompanied by payment in full of the aggregate Exercise Price of the Shares so purchased in cash or its equivalent, as determined by the Administrator. As determined by the Administrator, in its sole discretion, with respect to any Option or category of Options, payment in whole or in part may also be made (i) by means of consideration received under any cashless exercise procedure approved by the Administrator (including the withholding of Shares otherwise issuable upon exercise), (ii) in the form of unrestricted Shares already owned by the Participant which have a Fair Market Value on the date of surrender equal to the aggregate exercise price of the Shares as to which such Option shall be exercised, (iii) any other form of consideration approved by the Administrator and permitted by Applicable Laws or (iv) any combination of the foregoing.

(f) ISOs. The terms and conditions of ISOs granted hereunder shall be subject to the provisions of Section 422 of the Code and the terms, conditions, limitations and administrative procedures established by the Administrator from time to time in accordance with the Plan. At the discretion of the Administrator, ISOs may be granted only to an employee of the Company, its "parent corporation" (as such term is defined in Section 424(e) of the Code) or a Subsidiary of the Company.

(1) *ISO Grants to 10% Stockholders.* Notwithstanding anything to the contrary in the Plan, if an ISO is granted to a Participant who owns shares representing more than ten percent (10%) of the voting power of all classes of shares of the Company, its "parent corporation" (as such term is defined in Section 424(e) of the Code) or a Subsidiary of the Company, the term of the ISO shall not exceed five (5) years from the time of grant of such ISO and the Exercise Price shall be at least one hundred and ten percent (110%) of the Fair Market Value of the Shares on the date of grant.

(2) *$100,000 Per Year Limitation For ISOs*. To the extent the aggregate Fair Market Value (determined on the date of grant) of the Shares for which ISOs are exercisable for the first time by any Participant during any calendar year (under all plans of the Company) exceeds $100,000, such excess ISOs shall be treated as Nonqualified Stock Options.

(3) *Disqualifying Dispositions*. Each Participant awarded an ISO under the Plan shall notify the Company in writing immediately after the date the Participant makes a "disqualifying disposition" of any Share acquired pursuant to the exercise of such ISO. A "disqualifying disposition" is any disposition (including any sale) of such Shares before the later of (i) two years after the date of grant of the ISO and (ii) one year after the date the Participant acquired the Shares by exercising the ISO. The Company may, if determined by the Administrator and in accordance with procedures established by it, retain possession of any Shares acquired pursuant to the exercise of an ISO as agent for the applicable Participant until the end of the period described in the preceding sentence, subject to complying with any instructions from such Participant as to the sale of such Shares.

(g) Rights as Stockholder. A Participant shall have no rights to dividends, dividend equivalents or distributions or any other rights of a stockholder with respect to the Shares subject to an Option until the Participant has given written notice of the exercise thereof, and has paid in full for such Shares and has satisfied the requirements of Section 15 hereof.

(h) Termination of Employment or Service. Treatment of an Option upon termination of employment of a Participant shall be provided for by the Administrator in the Award Agreement.

(i) Other Change in Employment or Service Status. An Option shall be affected, both with regard to vesting schedule and termination, by leaves of absence, including unpaid and un-protected leaves of absence, changes from full-time to part-time employment, partial Disability or other changes in the employment status or service status of a Participant, in the discretion of the Administrator.

Section 8. **Share Appreciation Rights.**

(a) General. Share Appreciation Rights may be granted either alone ("Free Standing Rights") or in conjunction with all or part of any Option granted under the Plan ("Related Rights"). Related Rights may be granted either at or after the time of the grant of such Option. The Administrator shall determine the Eligible Recipients to whom, and the time or times at which, grants of Share Appreciation Rights shall be made. Each Participant who is granted a Share Appreciation Right shall enter into an Award Agreement with the Company, containing such terms and conditions as the Administrator shall determine, in its sole discretion, including, among other things, the number of Shares to be awarded, the Exercise Price per Share, and all other conditions of Share Appreciation Rights. Notwithstanding the foregoing, no Related Right may be granted for more Shares than are subject to the Option to which it relates. The provisions of Share Appreciation Rights need not be the same with respect to each Participant. Share Appreciation Rights granted under the Plan shall be subject to the following terms and conditions set forth in this Section 8 and shall contain such additional terms and conditions, not inconsistent with the terms of the Plan, as the Administrator shall deem desirable, as set forth in the applicable Award Agreement.

(b) Awards; Rights as Stockholder. A Participant shall have no rights to dividends or any other rights of a stockholder with respect to the shares of Common Stock, if any, subject to a Stock Appreciation Right until the Participant has given written notice of the exercise thereof and has satisfied the requirements of Section 15 hereof.

(c) Exercise Price. The Exercise Price of Shares purchasable under a Share Appreciation Rights shall be determined by the Administrator in its sole discretion at the time of grant, but in no event shall the exercise price of a Share Appreciation Rights be less than one hundred percent (100%) of the Fair Market Value of a share of Common Stock on the date of grant.

(d) Exercisability.

(1) Share Appreciation Rights that are Free Standing Rights shall be exercisable at such time or times and subject to such terms and conditions as shall be determined by the Administrator in the applicable Award Agreement.

(2) Share Appreciation Rights that are Related Rights shall be exercisable only at such time or times and to the extent that the Options to which they relate shall be exercisable in accordance with the provisions of Section 7 hereof and this Section 8 of the Plan.

(e) Payment Upon Exercise.

(1) Upon the exercise of a Free Standing Right, the Participant shall be entitled to receive up to, but not more than, that number of Shares equal in value to the excess of the Fair Market Value as of the date of exercise over the Exercise Price per share specified in the Free Standing Right multiplied by the number of Shares in respect of which the Free Standing Right is being exercised.

(2) A Related Right may be exercised by a Participant by surrendering the applicable portion of the related Option. Upon such exercise and surrender, the Participant shall be entitled to receive up to, but not more than, that number of Shares equal in value to the excess of the Fair Market Value as of the date of exercise over the Exercise Price specified in the related Option multiplied by the number of Shares in respect of which the Related Right is being exercised. Options which have been so surrendered, in whole or in part, shall no longer be exercisable to the extent the Related Rights have been so exercised.

(3) Notwithstanding the foregoing, the Administrator may determine to settle the exercise of a Share Appreciation Right in cash (or in any combination of Shares and cash).

(f) Termination of Employment or Service. Treatment of an Share Appreciation Right upon termination of employment of a Participant shall be provided for by the Administrator in the Award Agreement.

(g) Term.

(1) The term of each Free Standing Right shall be fixed by the Administrator, but no Free Standing Right shall be exercisable more than ten (10) years after the date such right is granted.

(2) The term of each Related Right shall be the term of the Option to which it relates, but no Related Right shall be exercisable more than ten (10) years after the date such right is granted.

(h) Other Change in Employment or Service Status. Share Appreciation Rights shall be affected, both with regard to vesting schedule and termination, by leaves of absence, including unpaid and un-protected leaves of absence, changes from full-time to part-time employment, partial Disability or other changes in the employment or service status of a Participant, in the discretion of the Administrator.

Section 9. **Restricted Shares and Restricted Stock Units.**

(a) General. Restricted Shares or Restricted Stock Units may be issued under the Plan. The Administrator shall determine the Eligible Recipients to whom, and the time or times at which, Restricted Shares or Restricted Stock Units shall be made. Each Participant who is granted Restricted Shares or Restricted Stock Units shall enter into an Award Agreement with the Company, containing such terms and conditions as the Administrator shall determine, in its sole discretion, including, among other things, the number of Shares to be awarded; the price, if any, to be paid by the Participant for the acquisition of Restricted Shares or Restricted Stock Units; the period of time restrictions, performance goals or other conditions that apply to Transferability, delivery or vesting of such Awards (the "Restricted Period"); and all other conditions applicable to the Restricted Shares and Restricted Stock Units. If the restrictions, performance goals or conditions established by the Administrator are not attained, a Participant shall forfeit his or her Restricted Shares or Restricted Stock Units, in accordance with the terms of the grant. The provisions of the Restricted Shares or Restricted Stock Units need not be the same with respect to each Participant.

(b) Awards and Certificates. Except as otherwise provided below in Section 9(c), (i) each Participant who is granted an Award of Restricted Shares may, in the Company's sole discretion, be issued a share certificate in respect of such Restricted Shares; and (ii) any such certificate so issued shall be registered in the name of the Participant, and shall bear an appropriate legend referring to the terms, conditions and restrictions applicable to any such Award. The Company may require that the share certificates, if any, evidencing Restricted Shares granted hereunder be held in the custody of the Company until the restrictions thereon shall have lapsed, and that, as a condition of any Award of Restricted Shares, the Participant shall have delivered a share transfer form, endorsed in blank, relating to the Shares covered by such Award. Certificates for shares of unrestricted Common Stock may, in the Company's sole discretion, be delivered to the Participant only after the Restricted Period has expired without forfeiture in such Restricted Stock Award. With respect to Restricted Stock Units to be settled in Shares, at the expiration of the Restricted Period, share certificates in respect of the shares of Common Stock underlying such Restricted Stock Units may, in the Company's sole discretion, be delivered to the Participant, or his legal representative, in a number equal to the number of shares of Common Stock underlying the Restricted Stock Units Award. Notwithstanding anything in the Plan to the contrary, any Restricted Shares or Restricted Stock Units to be settled in Shares (at the expiration of the Restricted Period, and whether before or after any vesting conditions have been satisfied) may, in the Company's sole discretion, be issued in uncertificated form. Further, notwithstanding anything in the Plan to the contrary, with respect to Restricted Stock Units, at the expiration of the Restricted Period, Shares, or cash, as applicable, shall promptly be issued (either in certificated or uncertificated form) to the Participant, unless otherwise deferred in accordance with procedures established by the Company in accordance with Section 409A of the Code, and such issuance or payment shall in any event be made

within such period as is required to avoid the imposition of a tax under Section 409A of the Code.

(c) Restrictions and Conditions. The Restricted Shares or Restricted Stock Units granted pursuant to this Section 9 shall be subject to the following restrictions and conditions and any additional restrictions or conditions as determined by the Administrator at the time of grant or, subject to Section 409A of the Code where applicable, thereafter:

(1) The Administrator may, in its sole discretion, provide for the lapse of restrictions in installments and may accelerate or waive such restrictions in whole or in part based on such factors and such circumstances as the Administrator may determine, in its sole discretion, including, but not limited to, the attainment of certain performance goals, the Participant's termination of employment or service with the Company or any Affiliate thereof, or the Participant's death or Disability. Notwithstanding the foregoing, upon a Change in Control, the outstanding Awards shall be subject to Section 12 hereof.

(2) Except as provided in the applicable Award Agreement, the Participant shall generally have the rights of a stockholder of the Company with respect to Restricted Shares during the Restricted Period; provided, however, that dividends declared during the Restricted Period with respect to an Award, shall only become payable if (and to the extent) the underlying Restricted Shares vest. Except as provided in the applicable Award Agreement, the Participant shall generally not have the rights of a stockholder with respect to Shares subject to Restricted Stock Units during the Restricted Period; provided, however, that, subject to Section 409A of the Code, an amount equal to dividends declared during the Restricted Period with respect to the number of Shares covered by Restricted Stock Units shall, unless otherwise set forth in an Award Agreement, be paid to the Participant at the time (and to the extent) Shares in respect of the related Restricted Stock Units are delivered to the Participant. Certificates for Shares of unrestricted Common Stock may, in the Company's sole discretion, be delivered to the Participant only after the Restricted Period has expired without forfeiture in respect of such Restricted Shares or Restricted Stock Units, except as the Administrator, in its sole discretion, shall otherwise determine.

(3) The rights of Participants granted Restricted Shares or Restricted Stock Units upon termination of employment or service as a director, independent contractor or consultant to the Company or to any Affiliate thereof terminates for any reason during the Restricted Period shall be set forth in the Award Agreement.

(d) Form of Settlement. The Administrator reserves the right in its sole discretion to provide (either at or after the grant thereof) that any Restricted Stock Unit represent the right to receive the amount of cash per unit that is determined by the Administrator in connection with the Award.

Section 10. **Other Share-Based Awards.**

Other Share-Based Awards may be issued under the Plan. Subject to the provisions of the Plan, the Administrator shall have sole and complete authority to determine the individuals to whom and the time or times at which such Other Share-Based Awards shall be granted. Each Participant who is granted an Other Share-Based Award shall enter into an Award Agreement with the Company, containing such terms and conditions as the Administrator shall determine, in its sole discretion, including, among other things, the number of shares of Common Stock to be granted pursuant to such Other Share-Based Awards, or the manner in which such Other Share-Based Awards shall be settled (e.g., in shares of Common Stock, cash or other property), or the conditions to the vesting and/or payment or settlement of such Other Share-Based Awards (which may include, but not be limited to, achievement of performance criteria) and all other terms and conditions of such Other Share-Based Awards. In the event that the Administrator grants a bonus in the form of Shares, the Shares constituting such bonus shall, as determined by the Administrator, be evidenced in uncertificated form or by a book entry record or a certificate issued in the name of the Participant to whom such grant was made and delivered to such Participant as soon as practicable after the date on which such bonus is payable. Notwithstanding anything set forth in the Plan to the contrary, any dividend or dividend equivalent Award issued hereunder shall be subject to the same restrictions, conditions and risks of forfeiture as apply to the underlying Award.

Section 11. **Cash Awards.**

The Administrator may grant Awards that are denominated in, or payable to Participants solely in, cash, as deemed by the Administrator to be consistent with the purposes of the Plan, and, such Cash Awards shall be subject to the terms, conditions, restrictions and limitations determined by the Administrator, in its sole discretion, from time to time. Awards granted pursuant to this Section 11 may be granted with value and payment contingent upon the achievement of performance goals.

Section 12. **Change in Control.**

Unless otherwise determined by the Administrator and evidenced in an Award Agreement, notwithstanding Section 4(e) of the Plan, in the event that (a) a Change in Control occurs, and (b) the Participant's employment or service is terminated by the Company, its successor or an Affiliate thereof without Cause or by the Participant for Good Reason (if applicable) on or after the effective date of the Change in Control but prior to twelve (12) months following the Change in Control, then:

(a) any unvested or unexercisable portion of any Award carrying a right to exercise shall become fully vested and exercisable; and

(b) the restrictions, deferral limitations, payment conditions and forfeiture conditions applicable to an Award granted under the Plan shall lapse and such Awards shall be deemed fully vested and any performance conditions imposed with respect to such Awards shall be deemed to be fully achieved at target performance levels.

If the Administrator determines in its discretion pursuant to Section 3(b)(4) hereof to accelerate the vesting of Options and/or Share Appreciation Rights in connection with a Change in Control, the Administrator shall also have discretion in connection with such action to provide that all Options and/or Share Appreciation Rights outstanding immediately prior to such Change in Control shall expire on the effective date of such Change in Control.

Section 13. **Amendment and Termination.**

The Board may amend, alter or terminate the Plan at any time, but no amendment, alteration or termination shall be made that would impair the rights of a Participant under any Award theretofore granted without such Participant's consent. The Board shall obtain approval of the Company's stockholders for any amendment that would require such approval in order to satisfy the requirements of any rules of the stock exchange on which the Common Stock is traded or other Applicable Law. The Administrator may amend the terms of any Award theretofore granted, prospectively or retroactively, but, subject to Section 5 of the Plan and the immediately preceding sentence, no such amendment shall materially impair the rights of any Participant without his or her consent.

Section 14. **Unfunded Status of Plan.**

The Plan is intended to constitute an "unfunded" plan for incentive compensation. With respect to any payments not yet made to a Participant by the Company, nothing contained herein shall give any such Participant any rights that are greater than those of a general creditor of the Company.

Section 15. **Withholding Taxes.**

Each Participant shall, no later than the date as of which the value of an Award first becomes includible in the gross income of such Participant for purposes of applicable taxes, pay to the Company, or make arrangements satisfactory to the Administrator regarding payment of an amount up to the maximum statutory tax rates in the Participant's applicable jurisdiction with respect to the Award, as determined by the Company. The obligations of the Company under the Plan shall be conditional on the making of such payments or arrangements, and the Company shall, to the extent permitted by Applicable Laws, have the right to deduct any such taxes from any payment of any kind otherwise due to such Participant. Whenever cash is to be paid pursuant to an Award, the Company shall have the right to deduct therefrom an amount sufficient to satisfy any applicable withholding tax requirements related thereto. Whenever Shares or property other than cash are to be delivered pursuant to an Award, the Company shall have the right to require the Participant to remit to the Company in cash an amount sufficient to satisfy any related taxes to be withheld and applied to the tax obligations; provided, that, with the approval of the Administrator, a Participant may satisfy the foregoing requirement by either (i) electing to have the Company withhold from delivery of Shares or other property, as applicable, or (ii) delivering already owned unrestricted shares of Common Stock, in each case, having a value not exceeding the applicable taxes to be withheld and applied to the tax obligations. Such already owned and unrestricted shares of Common Stock shall be valued at their Fair Market Value on the date on which the amount of tax to be withheld is determined and any fractional share amounts resulting therefrom shall be settled in cash. Such an election may be made with respect to all or any portion of the Shares to be delivered pursuant to an award. The Company may also use any other method of obtaining the necessary payment or proceeds, as permitted by Applicable Laws, to satisfy its withholding obligation with respect to any Award.

Section 16. **Transfer of Awards.**

Until such time as the Awards are fully vested and/or exercisable in accordance with the Plan or an Award Agreement, no purported sale, assignment, mortgage, hypothecation, transfer, charge, pledge, encumbrance, gift, transfer in trust (voting or other) or other disposition of, or creation of a security interest in or lien on, any Award or any agreement or commitment to do any of the foregoing (each, a "Transfer") by any holder thereof in violation of the provisions of the Plan or an Award Agreement will be valid, except with the prior written consent of the Administrator, which consent may be granted or withheld in the sole discretion of the Administrator. Any purported Transfer of an Award or any economic benefit or interest therein in violation of the Plan or an Award Agreement shall be null and void *ab initio* and shall not create any obligation or liability of the Company, and any Person purportedly acquiring any Award or any economic benefit or interest therein transferred in violation of the Plan or an Award Agreement shall not be entitled to be recognized as a holder of such Shares or other property underlying such Award. Unless otherwise determined by the Administrator in accordance with the provisions of the immediately preceding sentence, an Option or a Share Appreciation Right may be exercised, during the lifetime of the Participant, only by the Participant or, during any period during which the Participant is under a legal Disability, by the Participant's guardian or legal representative.

Section 17. **Continued Employment or Service.**

Neither the adoption of the Plan nor the grant of an Award shall confer upon any Eligible Recipient any right to continued employment or service with the Company or any Affiliate thereof, as the case may be, nor shall it interfere in any way with the right of the Company or any Affiliate thereof to terminate the employment or service of any of its Eligible Recipients at any time.

Section 18. **Effective Date.**

The Plan was adopted by the Board on May 18, 2021 and shall become effective upon the closing of the initial public offering (the "Effective Date").

Section 19. **Electronic Signature.**

Participant's electronic signature of an Award Agreement shall have the same validity and effect as a signature affixed by hand.

Section 20. **Term of Plan.**

No Award shall be granted pursuant to the Plan on or after the tenth anniversary of the Effective Date, but Awards theretofore granted may extend beyond that date.

Section 21. **Securities Matters and Regulations.**

(a) Notwithstanding anything herein to the contrary, the obligation of the Company to sell or deliver Shares with respect to any Award granted under the Plan shall be subject to all Applicable Laws, rules and regulations, including all applicable federal and state securities laws, and the obtaining of all such approvals by governmental agencies as may be deemed necessary or appropriate by the Administrator. The Administrator may require, as a condition of the issuance and delivery of certificates evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates bear such legends, as the Administrator, in its sole discretion, deems necessary or advisable.

(b) Each Award is subject to the requirement that, if at any time the Administrator determines that the listing, registration or qualification of Shares is required by any securities exchange or under any state or federal law, or the consent or approval of any governmental regulatory body is necessary or desirable as a condition of, or in connection with, the grant of an Award or the issuance of Shares, no such Award shall be granted or payment made or Shares issued, in whole or in part, unless listing, registration, qualification, consent or approval has been effected or obtained free of any conditions not acceptable to the Administrator.

(c) In the event that the disposition of Shares acquired pursuant to the Plan is not covered by a then current registration statement under the Securities Act and is not otherwise exempt from such registration, such Shares shall be restricted against transfer to the extent required by the Securities Act or regulations thereunder, and the Administrator may require a Participant receiving Common Stock pursuant to the Plan, as a condition precedent to receipt of such Common Stock, to represent to the Company in writing that the Common Stock acquired by such Participant is acquired for investment only and not with a view to distribution.

Section 22. **Section 409A of the Code.**

The Plan as well as payments and benefits under the Plan are intended to be exempt from, or to the extent subject thereto, to comply with Section 409A of the Code, and, accordingly, to the maximum extent permitted, the Plan shall be interpreted in accordance therewith. Notwithstanding anything contained herein to the contrary, to the extent required in order to avoid accelerated taxation and/or tax penalties under Section 409A of the Code, the Participant shall not be considered to have terminated employment or service with the Company for purposes of the Plan and no payment shall be due to the Participant under the Plan or any Award until the Participant would be considered to have incurred a "separation from service" from the Company and its Affiliates within the meaning of Section 409A of the Code. Any payments described in the

Plan that are due within the "short term deferral period" as defined in Section 409A of the Code shall not be treated as deferred compensation unless Applicable Law requires otherwise. Notwithstanding anything to the contrary in the Plan, to the extent that any Awards (or any other amounts payable under any plan, program or arrangement of the Company or any of its Affiliates) are payable upon a separation from service and such payment would result in the imposition of any individual tax and penalty interest charges imposed under Section 409A of the Code, the settlement and payment of such awards (or other amounts) shall instead be made on the first business day after the date that is six (6) months following such separation from service (or death, if earlier). Each amount to be paid or benefit to be provided under this Plan shall be construed as a separate identified payment for purposes of Section 409A of the Code. The Company makes no representation that any or all of the payments or benefits described in this Plan will be exempt from or comply with Section 409A of the Code and makes no undertaking to preclude Section 409A of the Code from applying to any such payment. The Participant shall be solely responsible for the payment of any taxes and penalties incurred under Section 409A.

Section 23. **Notification of Election Under Section 83(b) of the Code.**

If any Participant shall, in connection with the acquisition of shares of Common Stock under the Plan, make the election permitted under Section 83(b) of the Code, such Participant shall notify the Company of such election within ten (10) days after filing notice of the election with the Internal Revenue Service.

Section 24. **No Fractional Shares.**

No fractional shares of Common Stock shall be issued or delivered pursuant to the Plan. The Administrator shall determine whether cash, other Awards, or other property shall be issued or paid in lieu of such fractional shares or whether such fractional shares or any rights thereto shall be forfeited or otherwise eliminated.

Section 25. **Beneficiary.**

A Participant may file with the Administrator a written designation of a beneficiary on such form as may be prescribed by the Administrator and may, from time to time, amend or revoke such designation. If no designated beneficiary survives the Participant, the executor or administrator of the Participant's estate shall be deemed to be the Participant's beneficiary.

Section 26. **Paperless Administration.**

In the event that the Company establishes, for itself or using the services of a third party, an automated system for the documentation, granting or exercise of Awards, such as a system using an internet website or interactive voice response, then the paperless documentation, granting or exercise of Awards by a Participant may be permitted through the use of such an automated system.

Section 27. **Severability.**

If any provision of the Plan is held to be invalid or unenforceable, the other provisions of the Plan shall not be affected but shall be applied as if the invalid or unenforceable provision had not been included in the Plan.

Section 28. **Clawback.**

(a) If the Company is required to prepare a financial restatement due to the material non-compliance of the Company with any financial reporting requirement, then the Committee may require any Section 16 Officer to repay or forfeit to the Company, and each Section 16 Officer agrees to so repay or forfeit, that part of the Incentive Compensation received by that Section 16 Officer during the three-year period preceding the publication of the restated financial statement that the Committee determines was in excess of the amount that such Section 16 Officer would have received had such Incentive Compensation been calculated based on the financial results reported in the restated financial statement. The Committee may take into account any factors it deems reasonable in determining whether to seek recoupment of previously paid Incentive Compensation and how much Incentive Compensation to recoup from each Section 16 Officer (which need not be the same amount or proportion for each Section 16 Officer), including any determination by the Committee that a Section 16 Officer engaged in fraud, willful misconduct or committed grossly negligent acts or omissions which materially contributed to the events that led to the financial restatement. The amount and form of the Incentive Compensation to be recouped shall be determined by the Committee in its sole and absolute discretion, and recoupment of Incentive Compensation may be made, in the Committee's sole and absolute discretion, through the cancellation of vested or unvested Awards, cash repayment or both.

(b) Notwithstanding any other provisions in this Plan, any Award which is subject to recovery under any Applicable Laws, government regulation or stock exchange listing requirement, will be subject to such deductions and clawback as may be required to be made pursuant to such Applicable Law, government regulation or stock exchange listing requirement (or any policy adopted by the Company pursuant to any such law, government regulation or stock exchange listing requirement).

Section 29. **Governing Law.**

The Plan shall be governed by, and construed in accordance with, the laws of the State of Delaware, without giving effect to principles of conflicts of law of such state.

Section 30. **Indemnification.**

To the extent allowable pursuant to applicable law, each member of the Board and the Administrator and any officer or other employee to whom authority to administer any component of the Plan is delegated shall be indemnified and held harmless by the Company from any loss, cost, liability, or expense that may be imposed upon or reasonably incurred by such member in connection with or resulting from any claim, action, suit, or proceeding to which he or she may be a party or in which he or she may be involved by reason of any action or failure to act pursuant to the Plan and against and from any and all amounts paid by him or her in satisfaction of judgment in such action, suit, or proceeding against him or her; provided, however, that he or she gives the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such individuals may be entitled pursuant to the Company's Certificate of Incorporation or Bylaws, as a matter of law, or otherwise, or any power that the Company may have to indemnify them or hold them harmless.

Section 31. **Titles and Headings, References to Sections of the Code or Exchange Act.**

The titles and headings of the sections in the Plan are for convenience of reference only and, in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control. References to sections of the Code or the Exchange Act shall include any amendment or successor thereto.

Section 32. **Successors.**

The obligations of the Company under the Plan shall be binding upon any successor corporation or organization resulting from the merger, consolidation or other reorganization of the Company, or upon any successor corporation or organization succeeding to substantially all of the assets and business of the Company.

Section 33. **Relationship to other Benefits.**

No payment pursuant to the Plan shall be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare, or other benefit plan of the Company or any Affiliate except to the extent otherwise expressly provided in writing in such other plan or an agreement thereunder.

Exhibit 10.7

EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement"), dated May 18, 2021, is by and among Unicycive Therapeutics Inc., a Delaware corporation (the "Company"), and Shalabh Gupta (the "Executive").

WHEREAS, the Company desires to continue to employ Executive, and Executive desires to continue to be employed by, the Company, in each case effective as of the date of an initial public offering of the Company (the "Effective Date");

WHEREAS, in connection with the foregoing, Executive shall be required to perform Executive's duties and obligations hereunder on behalf of the Company, as appropriate, and such duties and obligations shall be enforceable by the Company;

WHEREAS, this Agreement supersedes any and all prior employment agreements or similar agreements by and between Executive and the Company;

NOW, THEREFORE, in consideration of such employment and the mutual covenants and promises herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and Executive agree that the above recitals are hereby incorporated by reference into this Agreement and are binding upon the parties hereto and agree as follows:

1. Employment. The Company hereby agrees to employ Executive, and Executive hereby agrees to be employed with the Company, upon the terms and conditions contained in this Agreement. Unless earlier terminated by either party in accordance with Section 5, Executive's employment with the Company shall continue for an initial term commencing on the Effective Date and continuing until the third (3rd) anniversary of the Effective Date (the "Initial Term") and thereafter shall automatically renew for successive one year terms (each a "Renewal Term") unless either party provides written notice of non-renewal to the other party at least sixty (60) days prior to the last day of the then-current term (such Initial Term and subsequent Renewal Term(s) or portions thereof occurring prior to termination, collectively the "Employment Period").

2. Duties.

2.1 During the Employment Period, Executive shall serve the Company on a full-time basis and perform services in a capacity and in a manner consistent with Executive's position for the Company. Executive shall have the title of Founder and Chief Executive Officer of the Company and shall have such duties, authorities and responsibilities as are consistent with such position, as the Board of Directors of the Company (the "Company Board") may designate from time to time. Executive will report directly to the Company Board. During the Employment Period, the Company Board shall recommend to its shareholders that Executive be elected as a member of the Company Board and, if so elected, Executive shall serve for no additional consideration as a member of the Company Board. Notwithstanding the foregoing, Executive may (i) serve as a director officer and/or advisor of one (1) for-profit company without the prior approval of the Company Board; (ii) perform and participate in charitable, civic, educational, professional, community and industry affairs and other related activities; and (iii) manage Executive's personal investments, provided, however, that such activities do not materially interfere, individually or in the aggregate with the performance of Executive's duties hereunder. Further notwithstanding the foregoing, nothing contained in this Agreement shall be construed to prevent Executive from being employed by or providing services to Globavir Biosciences, Inc., a Delaware corporation.

3. Location Of Employment. Executive shall work remotely until such time as Executive and the Company mutually agree that Executive will work from the Company offices.

4. Compensation.

4.1 Base Salary. In consideration of all services rendered by Executive under this Agreement, the Company shall pay Executive a base salary (the "Base Salary") at an annual rate of $550,000 during the Employment Period. The Base Salary shall be paid in such installments and at such times as the Company pays its regularly salaried employees, but no less often than once per month.

4.2 Annual Discretionary Bonus. During each fiscal year of the Executive's employment with the Company (commencing with the 2021 fiscal year), Executive will be eligible to receive an annual discretionary bonus ("Cash Bonus"). Executive's target Cash Bonus shall be equal to 100% of Base Salary (the "Target Bonus"). The Cash Bonus amount will be based upon achievement of Company and individual performance targets established by the Company Board, in its sole and absolute discretion, for the fiscal year to which the bonus relates. The payment of any Cash Bonus described herein will be made at the same time annual bonuses are generally paid to other senior executives of the Company (generally the first regular payroll date following the Company Board's certification of achievement of applicable performance targets). If Executive is eligible to receive a Cash Bonus, such bonus will not be deemed to be fully "earned" unless Executive is (i) employed by the Company and in good standing on the last day of the fiscal year to which the Cash Bonus relates, and (ii) has not given notice of Executive's intention to resign Executive's employment as of, or prior to, the date the Company pays the applicable Cash Bonus. The Cash Bonus shall be paid to Executive no later than March 15th of the year following the year for which the bonus is payable.

4.3 Equity Award. Executive will, on or as soon as reasonably practicable after the date of an initial public offering of the Company (the "IPO Date"), be granted an equity-based compensation award ("Award") in such amounts and subject to such terms and conditions that are consistent with, and no less favorable to Executive than, the terms and conditions set forth in Exhibit A attached hereto. Upon termination of Executive's employment, the treatment of any portion of outstanding Award shall be determined in accordance with the terms of any agreements governing such Award (" Award Agreement"). Executive shall remain eligible to receive additional equity-based compensation awards as the Company may grant from time to time.

4.4 Vacation. During the Employment Period, Executive shall be entitled to vacation benefits consistent with Company policy, as may be in effect from time to time, except to the extent such policy is inconsistent with this Agreement.

4.5 Benefits. During the Employment Period, Executive shall be entitled to participate in any benefit plans offered by the Company as in effect from time to time (collectively, "Benefit Plans") on the same basis as those generally made available to other senior employees of the Company, to the extent Executive may be eligible to do so under the terms of any such Benefit Plan. Executive acknowledges and agrees that any such Benefit Plans may be terminated or amended from time to time by the Company in its sole discretion. During the Employment Period, the Company shall provide Executive with (i) life insurance coverage (equal to at least two (2) times Executive's Base Salary), and (ii) disability insurance coverage. The Company will cover Executive under directors' and officers' liability insurance, with Executive as a named insured, during Executive's employment (and for a period of six (6) years following the termination thereof), to the same general extent as other executive officers of the Company.

5. Termination. Executive's employment hereunder may be terminated as follows:

5.1 Automatically in the event of the death of Executive;

5.2 At the option of the Company, by written notice to Executive or Executive's personal representative in the event of the Disability of Executive. As used herein, the term "Disability" shall mean a determination by an independent competent medical authority (mutually agreed upon by Executive and the Company) that Executive is unable to perform Executive's duties under this Agreement with or without reasonable accommodation, for a period of 120 consecutive days or 180 days in any 365 day period. If there is a question as to the existence of Executive's Disability as to which Executive and the Company cannot agree, same shall be determined in writing by a qualified independent medical authority mutually acceptable to Executive and the Company. If the parties hereto cannot agree as to a qualified independent physician, each of the Executive, on the one hand, and the Company, on the other, shall appoint such a physician and those two physicians shall select a third who shall make such determination in writing. The determination of Disability made in writing to the Company and Executive shall be final and conclusive for all purposes of this Agreement. Executive shall fully cooperate in connection with the determination of whether Disability exists.

5.3 At the option of the Company for Cause (as defined in Section 6.6), on prior written notice to Executive (subject to any cure period described in Section 6.6);

5.4 At the option of the Company without Cause, on thirty (30) days' prior written notice to Executive;

5.5 At the option of Executive (a) for Good Reason (in accordance with the definition in Section 6.5) or (b) for any or no reason other than Good Reason on thirty (30) days' prior written notice to the Company (which the Company may, in its sole discretion, make effective as a resignation earlier than the termination date provided in such notice and further provided that if Executive unilaterally resigns Executive's employment before the end of such requisite notice period then such resignation shall be treated for purposes of this Agreement as a termination under Section 5.4); or

5.6 As of the last day of the Initial Term or the then-current Renewal Term if either Executive or the Company elects not to renew the Agreement in accordance with and subject to the notice provisions set forth in Section 1.

6. Severance Payments.

6.1 Non-Renewal by the Company, Termination by the Company Without Cause or Termination by Executive for Good Reason. If Executive's employment is terminated by the Company without Cause (and not due to death or Disability), by Executive for Good Reason or as the result of the Company's decision not to renew the Agreement in accordance with Section 1, subject to Section 6.7 hereof, Executive shall be entitled to:

(a) within thirty (30) days following such termination, payment of Executive's accrued and unpaid Base Salary and reimbursement of expenses under Section 7 hereof in each case accrued through the date of termination;

(b) subject to Section 13.7(b) hereof, an amount in cash equal to the product of one and one-half (1.5) times the sum of (i) Executive's Base Salary and (ii) Executive's Target Bonus (in each case, as in effect as of Executive's last day of employment), which shall be payable in substantially equal installments (the " Severance Amount") at the same time Base Salary would be paid over the eighteen (18) month period (the "Severance Period") following termination; provided, however, if the Executive's review and revocation period for the release of claims required pursuant to Section 6.7 hereof spans two of Executive's taxable years, the first payment shall be made on the first regularly scheduled payroll date of the later taxable year following the effective date of such release of claims and shall include all amounts accrued prior thereto;

(c) if Executive is eligible for and elects to enroll in "COBRA" type continuation coverage of Executive's health benefits under the Company's group health plan, for the Severance Period ("COBRA Payment Period") the Company will pay Executive on a monthly basis a taxable amount equal to the full monthly premium for the corresponding active employee coverage type (e.g., single, single plus one, family) under the Company's group health plan that was in effect for Executive on the termination date, less applicable taxes and withholdings; provided, that the Company's obligation to make these monthly taxable COBRA premium payments to Executive hereunder shall cease on the earlier of: (i) the date on which Executive first becomes eligible for coverage under any group health plan made available by another employer (and Executive shall notify the Company in writing promptly, but within 10 days, after becoming eligible for any such benefits); and (ii) the date on which Executive's COBRA continuation coverage under the Company's group health plan ends on account of Executive's election to terminate such coverage; notwithstanding the foregoing, if the Company determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Internal Revenue Code of 1986, as amended (the "Code") or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums; the Company, in its sole discretion, may elect to instead pay Executive on the first day of each month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings (such amount, the "Special Severance Payment"), for the remainder of the COBRA Payment Period (Executive may, but is not obligated to, use such Special Severance Payment toward the cost of COBRA premiums); notwithstanding the foregoing, if for any reason Executive is ineligible for, or does not elect to enroll in "COBRA" type continuation coverage of Executive's health benefits under the Company's group health plan, the Company will pay Executive a lump sum equal to the aggregate payments the Company would have paid Executive on a monthly basis pursuant to the above provisions;

(d) a lump sum payment equal to the amount of any Cash Bonus earned with respect to a fiscal year ending prior to the date of such termination but unpaid as of such date, payable at the same time in the year of termination as such payment would be made if Executive continued to be employed by the Company, but in no event later than 73 days following the end of the fiscal year in which the termination occurs;

(e) a lump sum payment equal to the amount of Cash Bonus that was accrued for the year in which Executive's employment ends based upon the good faith determination of the Company Board in accordance with the Company's normal practices as of the last day of the calendar month during which Executive's termination became effective (it being understood that the Company will accrue the Cash Bonus on a monthly basis), payable no later than 73 days after the termination date;

(f) all other accrued or vested amounts or benefits due to Executive in accordance with this Agreement, the Company's benefit plans, programs or policies (other than severance), and the treatment of Executive's Award in accordance with the Award Agreement; and

(g) subject to Executive's compliance with the restrictive covenants set forth in Section 8 hereof, the outstanding and unvested portion of any time-vesting equity award granted to Executive by the Company shall automatically accelerate and vest in full upon Executive's termination date.

6.2 Termination due to Executive's Death or Disability. Upon the termination of Executive's employment due to Executive's death or Disability pursuant to Section 5.1 and Section 5.2 respectively, Executive or Executive's legal representatives shall be entitled to receive (i) the acceleration and vesting in full of any then outstanding and unvested portion of any time-vesting equity award granted to Executive by the Company; and (ii) the payments and benefits described under Sections 6.1(a), (d), (e) and (f).

6.3 Termination due to Non-Renewal by Executive or Termination by Executive without Good Reason. Upon the termination of Executive's employment due to the non-renewal by Executive or termination by Executive without Good Reason, Executive shall be entitled to receive only the payments and benefits described in Sections 6.1(a), (d), and (f), and the treatment of Executive's Award in accordance with the Award Agreement.

6.4 Termination by the Company for Cause. Upon the termination of Executive's employment by the Company for Cause pursuant to Section 5.3, Executive shall be entitled to receive only the payments and benefits described in Sections 6.1(a) and (f), and the treatment of Executive's Award in accordance with the Award Agreement.

6.5 Termination Following Change in Control. If Executive's employment is terminated by the Company without Cause or by Executive for Good Reason within twelve (12) months following a Change in Control, Executive shall be entitled to receive the following:(i) the acceleration and vesting in full of any then outstanding and unvested portion of any time- vesting equity award granted to Executive by the Company; (ii) the benefits described in Section 6.1(b) and (c), provided, however, that the Severance Amount shall equal two (2) times the sum of Base Salary and Target Bonus and the Severance Period shall be twenty-four (24) months; and (iii) the benefits described in Section 6.1(a), (d), (e) and (f).

6.6 Definitions.

(a) Cause. For purposes of this Agreement, "Cause" shall mean:

(i) Executive's continued failure or refusal to follow the lawful directives of the Company Board after being given written notice and thirty (30) days to remedy such failures or refusals;

(ii) Executive's willful misconduct, gross negligence, act of material dishonesty in connection with Executive's employment;

(iii) Executive's indictment for, or a plea of guilty or no contest to, any felony or any other criminal offence involving serious moral turpitude;

(iv) Executive's violation of any material written policies of the Company or its affiliates of which Executive has received written notice and which violation is, in each case, if curable, is not cured within thirty (30) days of written notice from the Company;

(v) Executive's breach of any non-solicitation or non-competition obligations to the Company or its affiliates, including, without limitation, those set forth in Sections 8.1 and 8.2 of this Agreement or Executive's willful, grossly negligent, or reckless breach of any confidentiality obligations to the Company or its affiliates, including, without limitation, those set forth in Section 8.3 of this Agreement;

(vi) material breach by Executive of any of the provisions of this Agreement or any other agreement between the Company and its affiliates on the one hand and Executive on the other hand, which (if curable) is not cured within thirty (30) days of written notice; or

(vii) as provided in Section 13.1 hereof.

(b) "Change in Control" shall have the meaning given that term in the Company's 2021 Omnibus Equity Incentive Plan.

(c) "Good Reason" shall mean, without Executive's prior written consent, (i) a material diminution in Executive's title, authority, duties or responsibilities; (ii) a materialreduction in Base Salary; (iii) a material reduction in the target percentage of the Executive's Cash Bonus; (iv) the relocation of Executive's principal place of employment more than fifty(50) miles from its then current location; or (v) a breach by the Company of any material provision of this Agreement (the parties agreeing that Section 4.1 is one such material provision). Any Good Reason termination will require thirty (30) days' advanced written notice by Executive of the event giving rise to Good Reason within sixty (60) days after Executive first learns of the applicable event, and will not be effective unless the Company has not cured the Good Reason event within such thirty (30) day notice period. In order for Executive to resign for Good Reason, Executive must resign from Executive's employment within sixty (60) days after the failure of the Company to cure a Good Reason event.

(d) "Person" means any natural person, sole proprietorship, general partnership, limited partnership, limited liability company, joint venture, trust, unincorporated organization, association, corporation, governmental authority or any other organization, irrespective of whether it is a legal entity and includes any successor (by merger or otherwise) of such entity.

6.7 Conditions to Payment. All payments and benefits due to Executive under this Section 6, other than the payments due to Executive under Sections 6.1(a), (d), and (f) or which are otherwise required by law (all other payments under Section 6, "Severance"), shall only be payable if Executive (or Executive's beneficiary or estate) delivers to the Company and does not revoke (under the terms of applicable law) a general release of all claims substantially in the form attached hereto as Exhibit B. Such general release shall be executed and delivered (and no longer subject to revocation) within fifty-five (55) days following termination. Failure to timely execute and return such release or revocation thereof shall be a waiver by Executive of Executive's right to receive any Severance. In addition, Severance shall be conditioned on Executive's compliance with Section 8 hereof.

7. Reimbursement of Expenses. The Company shall reimburse Executive for reasonable and necessary expenses actually incurred by Executive directly in connection with the business and affairs of the Company and the performance of Executive's duties hereunder, in each case subject to appropriate substantiation and itemization of such expenses in accordance with the guidelines and limitations established by the Company from time to time.

8. Restrictions on Activities of Executive.

8.1 Non-Competition. During employment and for the one (1) year period commencing on the date Executive's employment with the Company pursuant to this Agreement ends (except in the event Executive's employment ends due to Executive's Disability) (the "Restriction Period"), Executive covenants and agrees that Executive shall not directly or indirectly (whether for compensation or otherwise) own or hold any interest in, manage, operate, control, consult with, render services for, or in any manner participate in, any Competitive Business, in each case, either as a general or limited partner, proprietor, shareholder, officer, director, agent, employee, consultant, trustee, affiliate or otherwise. The Company may opt to extend the Restriction Period for up to an additional one (1) year period, provided that in such case Company shall also increase the Severance Amount and the Severance Period by one- twelfth (1/12) for each month that the Restricted Period is lengthened. For clarification, if Executive is not otherwise entitled to a Severance Amount, the Company shall pay Executive an amount equal to one-twelfth (1/12) of Executive's Base Salary for each month the Restricted Period is lengthened. Nothing herein shall prohibit Executive from being a passive owner of not more than one percent (1%) of the outstanding securities of any publicly traded company engaged in a Competitive Business. For purposes of this Agreement, "Competitive Business" shall mean the licensing and/or development of (x) the same or substantially similar compounds as those which the Company is then currently licensing or developing, or (y) compounds which the Company is then currently actively

considering licensing and/or developing, by virtue of management executives having held material discussions with applicable counterparties to license such compounds and material discussions with members of the Company Board regarding the same during the prior six (6) month period and of which Executive is aware; in each case, with respect to the same or similar indications for which the Company is then licensing, developing or considering the licensing and/or development of such compounds.

8.2 Non-Solicitation. Executive covenants and agrees that, except in connection with the performance of Executive's duties to the Company, during the Restriction Period, Executive shall not directly or indirectly (i) influence or attempt to influence or solicit any employees or independent contractors of the Company or any of its affiliates to restrict, reduce, sever or otherwise alter their relationship with the Company or such affiliates, (ii) hire any employees or independent contractors of the Company or any of its affiliates, (iii) solicit or induce, or attempt to solicit or induce, any Person that is then a client or customer of the Company, or any of its affiliates to cease being a client or customer of the Company or any of its affiliates or to divert all or any part of such Person's business from the Company or any of its affiliates, or (iv) assist any other Person in any way to do, or attempt to do, anything prohibited by Sections 8.2(i), (ii), or (iii); provided, however, that the foregoing restrictions shall not include (A) general solicitations of employment or hiring of persons responding to general solicitations of employment (including general advertising via periodicals, the Internet and other media) not specifically directed towards employees of the Company or its affiliates, or (B) serving as a third-party reference for any employee or independent contractor or providing advice to any employees.

8.3 Confidentiality. Executive shall not, during the Employment Period or at any time thereafter directly or indirectly, disclose, reveal, divulge or communicate to any Person other than authorized officers, directors and employees of the Company or use or otherwise exploit for Executive's own benefit or for the benefit of anyone other than the Company, any Confidential Information (as defined below). "Confidential Information" means any information with respect to the Company or any of its affiliates, including methods of operation, customer lists, products, prices, fees, costs, technology, formulas, inventions, trade secrets, know-how, software, marketing methods, plans, personnel, suppliers, competitors, markets or other specialized information or proprietary matters; provided, that, there shall be no obligation hereunder with respect to, information that (i) is generally available to the public on the Effective Date, (ii) becomes generally available to the public other than as a result of a disclosure not otherwise permissible hereunder, or (iii) is required to be disclosed by law, court order or other legal or regulatory process and Executive gives the Company prompt written notice and the opportunity to seek a protective order. For the avoidance of doubt, Executive understands that pursuant to the federal Defend Trade Secrets Act of 2016, Executive shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Nothing contained in this Agreement shall limit Executive's ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company. Further, nothing in this Agreement shall be deemed to preclude Executive from testifying truthfully under oath if Executive is required or compelled by law to testify in any judicial action or before any government authority or agency or from making any other legally-required truthful statements or disclosures.

8.4 Assignment of Inventions.

(a) Executive agrees that during employment with the Company, any and all inventions, discoveries, innovations, writings, domain names, improvements, trade secrets, designs, drawings, formulas, business processes, secret processes and know-how, whether or not patentable or a copyright or trademark, which Executive may create, conceive, develop or make, either alone or in conjunction with others and related or in any way connected with the Company's strategic plans, products, processes or apparatus or the business (collectively, "Inventions"), shall be fully and promptly disclosed to the Company and shall be the sole and exclusive property of the Company as against Executive or any of Executive's assignees. Regardless of the status of Executive's employment by the Company, Executive and Executive's heirs, assigns and representatives shall promptly assign to the Company any and all right, title and interest in and to such Inventions made during employment with the Company.

(b) Whether during or after the Employment Period, Executive further agrees to execute and acknowledge all papers and to do, at the Company's expense, any and all other things necessary for or incident to the applying for, obtaining and maintaining of such letters patent, copyrights, trademarks or other intellectual property rights, as the case may be, and to execute, on request, all papers necessary to assign and transfer such Inventions, copyrights, patents, patent applications and other intellectual property rights to the Company and its successors and assigns. In the event that the Company is unable, after reasonable efforts and, in any event, after ten (10) business days, to secure Executive's signature on a written assignment to the Company, of any application for letters patent, trademark registration or to any common law or statutory copyright or other property right therein, whether because of Executive's physical or mental incapacity, or for any other reason whatsoever, Executive irrevocably designates and appoints the Secretary of the Company as Executive's attorney-in-fact to act on Executive's behalf to execute and file any such applications and to do all lawfully permitted acts to further the prosecution or issuance of such assignments, letters patent, copyright or trademark.

8.5 Return of Company Property. Within ten (10) days following the date of any termination of Executive's employment, Executive or Executive's personal representative shall return all property of the Company and its affiliates in Executive's possession, including but not limited to all Company-owned computer equipment (hardware and software), smart phones, facsimile machines, tablet computers and other communication devices, credit cards, office keys, security access cards, badges, identification cards and all copies (including drafts) of any documentation or information (however stored) relating to the business of the Company and its affiliates, its customers and clients or its prospective customers and clients. Anything to the contrary notwithstanding, Executive shall be entitled to retain (i) personal papers and other materials of a personal nature, provided that such papers or materials do not include Confidential Information, (ii) information showing Executive's compensation or relating to reimbursement of expenses, and (iii) copies of plans, programs and agreements relating to Executive's employment, or termination thereof, with the Company which Executive received in Executive's capacity as a participant.

8.6 Cooperation. During the Employment Period and for six years thereafter, Executive shall give Executive's assistance and cooperation, upon reasonable advance notice, in any litigation matter relating to Executive's position with the Company and its affiliates, or Executive's knowledge as a result thereof as the Company may reasonably request, including Executive's attendance and truthful testimony where deemed appropriate by the Company, with respect to any investigation or the Company's (or an affiliate's) defense or prosecution of any existing or future claims or litigations or other proceeding relating to matters in which Executive was involved or had knowledge by virtue of Executive's employment with the Company, in all cases on schedules that are reasonably consistent with Executive's other permitted activities and commitments. The Company agrees to reimburse Executive for any costs Executive incurs in connection with complying with this Section, including Executive's reasonable attorney's fees. If Executive's compliance with this Section requires Executive to expend more than ten (10) hours (any time in excess of ten (10) hours, "Excess Time") in any quarter of a calendar year, the Company agrees to compensate Executive for such Excess Time at an hourly rate that is equal to the prorata rate the Executive earned while under employment with the Company.

8.7 Non-Disparagement. During Executive's employment with the Company, and at all times thereafter, (i) Executive shall not make either orally or in writing any

derogatory or disparaging statement with regard to the Company, any of its businesses, products, services or practices or any of its managers, directors, officers, employees or agents, and (ii) the Company shall direct the members of the Company Board and its senior executives not to make either orally or in writing any derogatory or disparaging statement with regard to the Executive, provided that nothing in this Section 8.7 shall prevent either party from giving a deposition, responding to any subpoena or other lawful request for information or documentation made in the course of a legal or administrative proceeding or testifying in court or in any other legal proceeding.

8.8 Survival. This Section 8 shall survive any termination or expiration of this Agreement or employment of Executive.

9. Remedies. It is specifically understood and agreed that any breach of the provisions of Section 8 of this Agreement is likely to result in irreparable injury to the Company and that the remedy at law alone will be an inadequate remedy for such breach, and that in addition to any other remedy it may have in the event of a breach or threatened breach of Section 8 above, the Company shall be entitled to enforce the specific performance of this Agreement by Executive and to seek both temporary and permanent injunctive relief (to the extent permitted by law) without bond and without liability should such relief be denied, modified or violated.

10. Blue Pencil. Each of the rights enumerated in this Agreement shall be independent of the others and shall be in addition to and not in lieu of any other rights and remedies available to the Company or any of its direct or indirect subsidiaries at law or in equity. If any of the provisions of this Agreement or any part of any of them is hereafter construed or adjudicated to be invalid or unenforceable because of the duration of such provisions or the area or scope covered thereby, Executive agrees that the court making such determination shall have the power to reduce the duration, scope and/or area of such provisions to the maximum and/or broadest duration, scope and/or area permissible by law, and in its reduced form said provision shall then be enforceable.

11. Severable Provisions. The provisions of this Agreement are severable and the invalidity of any one or more provisions shall not affect the validity of any other provision. In the event that a court of competent jurisdiction shall determine that any provision of this Agreement or the application thereof is unenforceable in whole or in part because of the duration or scope thereof, the parties hereto agree that said court in making such determination shall have the power to reduce the duration and scope of such provision to the extent necessary to make it enforceable, and that the Agreement in its reduced form shall be valid and enforceable to the full extent permitted by law.

12. Notices. All notices hereunder, to be effective, shall be in writing and shall be deemed effective when delivered by hand or mailed by (a) certified mail, postage and fees prepaid, or (b) nationally recognized overnight express mail service, as follows:

If to the Company:

Unicycive Therapeutics Inc.
5150 El Camino Real, Suite #A-32 Los Altos, CA 94022
Attention: Chief Executive Officer

with a copy (which shall not constitute notice) to:

Sheppard, Mullin, Richter & Hampton LLP 30 Rockefeller Plaza
New York, New York 10112 Attention: Jeffrey Fessler, Esq. Facsimile: 917.438.6133
Telephone: 212.634.3067
E-mail: jfessler@sheppardmullin.com If to Executive:
The last address shown on records of the Company

or to such other address as a party may notify the other pursuant to a notice given in accordance with this Section 12.

13. Miscellaneous.

13.1 Executive Representation. Executive hereby represents to the Company that Executive's execution and delivery of this Agreement and Executive's performance of Executive's duties hereunder shall not constitute a breach of, or otherwise contravene, or be prevented, interfered with or hindered by, the terms of any employment agreement or other agreement or policy to which Executive is a party or otherwise bound, and further that Executive is not subject to any limitation on Executive's activities on behalf of the Company as a result of agreements into which Executive has entered except for obligations of confidentiality with former employers. To the extent this representation and warranty is not true and accurate, it shall be treated as a Cause event and the Company may terminate Executive for Cause or not permit Executive to commence employment.

13.2 No Mitigation or Offset. In the event of any termination of Executive's employment hereunder, Executive shall be under no obligation to seek other employment or otherwise mitigate the obligations of the Company under this Agreement, and there shall be no offset against amounts due Executive under this Agreement on account of future earnings by Executive.

13.3 Entire Agreement; Amendment. Except as otherwise expressly provided herein, this Agreement constitutes the entire agreement between the parties hereto with regard to the subject matter hereof, superseding all prior understandings and agreements, whether written or oral. This Agreement may not be amended or revised except by a writing signed by the parties.

13.4 Assignment and Transfer. The provisions of this Agreement shall be binding on and shall inure to the benefit of the Company and any successor in interest to the Company who acquires all or substantially all of the Company's assets. The Company may assign this Agreement to an affiliate. Neither this Agreement nor any of the rights, duties or obligations of Executive shall be assignable by Executive, nor shall any of the payments required or permitted to be made to Executive by this Agreement be encumbered, transferred or in any way anticipated, except as required by applicable law. All rights of Executive under this Agreement shall inure to the benefit of and be enforceable by Executive's personal or legal representatives, estates, executors, administrators, heirs and beneficiaries.

13.5 Waiver of Breach. A waiver by either party of any breach of any provision of this Agreement by the other party shall not operate or be construed as a waiver of any other or subsequent breach by the other party.

13.6 Withholding. The Company shall be entitled to withhold from any amounts to be paid or benefits provided to Executive hereunder any federal, state, local or foreign withholding, FICA and FUTA contributions, or other taxes, charges or deductions which it is from time to time required to withhold.

13.7 Code Section 409A.

(a) The parties agree that this Agreement shall be interpreted to comply with or be exempt from Section 409A of the Code and the regulations and guidance promulgated thereunder to the extent applicable (collectively "Code Section 409A"), and all provisions of this Agreement shall be construed in a manner consistent with the requirements for avoiding taxes or penalties under Code Section 409A. In no event whatsoever will the Company be liable for any additional tax, interest or penalties that may be imposed on Executive under Code Section 409A or any damages for failing to comply with Code Section 409A.

(b) A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits considered "nonqualified deferred compensation" under Code Section 409A upon or following a termination of employment unless such termination is also a "separation from service" within the meaning of Code Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment" or like terms shall mean "separation from service." If Executive is deemed on the date of termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B), then with regard to any payment or the provision of any benefit that is considered nonqualified deferred compensation under Code Section 409A payable on account of a "separation from service," such payment or benefit shall be made or provided at the date which is the earlier of (i) the expiration of the six (6)-month period measured from the date of such "separation from service" of Executive, and (ii) the date of Executive's death (the "Delay Period"). Upon the expiration of the Delay Period, all payments and benefits delayed pursuant to this Section 13.7(b) (whether they would have otherwise been payable in a single sum or in installments in the absence of such delay) shall be paid or reimbursed on the first business day following the expiration of the Delay Period to Executive in a lump sum, and any remaining payments and benefits due under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein.

(c) With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Code Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits, to be provided in any other taxable year, provided, that, this clause (ii) shall not be violated with regard to expenses reimbursed under any arrangement covered by Internal Revenue Code Section 105(b) solely because such expenses are subject to a limit related to the period the arrangement is in effect and (iii) such payments shall be made on or before the last day of Executive's taxable year following the taxable year in which the expense occurred.

(d) For purposes of Code Section 409A, Executive's right to receive any installment payments pursuant to this Agreement shall be treated as a right to receive a series of separate and distinct payments. Whenever a payment under this Agreement specifies a payment period with reference to a number of days (e.g., "payment shall be made within thirty (30) days following the date of termination"), the actual date of payment within the specified period shall be within the sole discretion of the Company.

13.8 Arbitration. If any contest or dispute arises between the parties with respect to this Agreement or Executive's employment or termination thereof, other than injunctive and equitable relief with regard to Section 9 hereof, such contest or dispute shall be submitted to binding arbitration to occur in San Francisco, California before a single arbitrator in accordance with the rules and procedures of the Employment Dispute Resolution Rules of the American Arbitration Association (" AAA") then in effect. The decision of the arbitrator shall be final and binding on the parties and may be entered in any court of applicable jurisdiction. The parties shall bear their own legal fees in any arbitration.

13.9 Indemnification. On May 18, 2021, Executive and the Company entered into an indemnification agreement the "Indemnification Agreement") substantially in the form attached hereto as Exhibit C. The Company shall to the maximum extent permitted by applicable law indemnify and hold harmless Executive as provided in the Indemnification Agreement.

13.10 Governing Law. This Agreement shall be construed under and enforced in accordance with the laws of the State of California, without regard to the conflicts of law provisions thereof.

13.11 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and shall have the same effect as if the signatures hereto and thereto were on the same instrument.

[remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the day and year first above written.

UNICYCIVE THERAPEUTICS INC.

By: /s/ John Ryan
Name: John Ryan
Title: Board Member

EXECUTIVE

/s/ Shalabh Gupta, M.D.

EXHIBIT A

EQUITY TERMS

Type of Award ("Award")	• An award of stock options under the Company's 2021 Omnibus Equity Incentive Plan will be made available for Company senior management team. • Executive's Award to equal 500,000 shares.

	● Award is evidenced by agreement executed by Executive and the Company.
Vesting of Award	● The Award shall vest in equal one-third (1/3) installments on the first, second and third anniversaries of the Date of Grant (as defined in the applicable award agreement), subject to acceleration of vesting in the circumstances set forth below. ● Unless Executive forfeits the vested portion of the Award due to a termination for Cause or a breach of the restrictive covenants, the vested portion of the Award will remain exercisable for a period of twelve (12) months from the date of termination of Executive's employment.
Termination of Service for Cause, resignation with/without cause, death & disability, etc.	● Following termination of employment, Executive's Award shall vest with respect to that portion of the Award that would have vested during the one (1) year period following Executive's termination had Executive remained an employee; provided, however, that if Executive is terminated for Cause (as such term is defined in Executive's employment agreement) or breaches any restrictive covenants, then any outstanding portion of the Award will be forfeited for no consideration. In the event Executive's employment is terminated due to death or Disability, or in the event Executive's employment is terminated without Cause or Executive resigns for Good Reason within one (1) year of a Change in Control, the Award shall become fully vested.

EXHIBIT B

GENERAL RELEASE OF CLAIMS

GENERAL RELEASE and WAIVER (this "Agreement") made as of_____ , by and between Shalabh Gupta (the "Employee") and Unicycive Therapeutics Inc. (the "Employer," together with the Employee, the "Parties").

WHEREAS, Employee and the Employer have agreed that Employee's employment with the Company has been terminated;

WHEREAS, Employee and the Employer have previously entered into an Employment Agreement dated , 2021, as may have been amended or supplemented from time to time (the "Employment Agreement"), with any terms used, but not defined herein, having the meaning set forth in the Employment Agreement; and

WHEREAS, the Parties desire to enter into this Agreement, in satisfaction of all obligations of the Employee and the Employer in respect of Employee's employment with the Employer.

NOW, THEREFORE, in consideration of the mutual covenants set forth herein and for other good and valuable consideration, receipt of which is hereby acknowledged, the Employer and the Employee agree as follows:

1. Separation

(a) *Date of Separation*. Employee's employment with the Employer and all of its subsidiaries and affiliates will end on [DATE] (the "Termination Date"). Employee hereby acknowledges and agrees that Employee has resigned, effective as of the Termination Date, from any and all positions and titles Employee holds with the Employer and all of its affiliates (together, "Company Entities").

(b) *Severance*. In consideration for, subject to and conditioned on Employee's execution of this Agreement on or within twenty-one (21) days following the Termination Date, Employee's non-revocation thereof and compliance with such other conditions as are set forth in the Employment Agreement, Employee is eligible to receive the Severance in accordance with the terms and conditions set forth in the Employment Agreement.

(c) Full Satisfaction. The Employee acknowledges and agrees that, except for **[TO INCLUDE RIGHTS WITH RESPECT TO AWARD IF ANY ARE VESTED ("Equity Rights")]** the payments and benefits under Sections 6.1(a), (d), (f) and (g) of the Employment Agreement, or under Section 6.5 of the Employment Agreement in the event that a Termination occurs within twelve (12) months following a Change in Control, and except for Severance, the Employee is not entitled to any other compensation or benefits from the Company Entities (including without limitation any severance or termination compensation or benefits under any severance plan, program, policies, practices or arrangements of any of the Company Entities).

(d) *COBRA*. Pursuant to the applicable group plan terms and conditions, Employee will cease participating in Employer's health insurance plans as of the Termination Date. If applicable, the Employer will send the Employee documentation under separate cover relating to the Employee's rights pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA").

2. General Release and Waiver

(a) *Release*.

i. In exchange for and in consideration of the promises and covenants set forth in this Agreement and the Employment Agreement, and except as expressly set forth herein, Employee irrevocably and unconditionally releases and discharges the Company Entities and each of their subsidiaries, divisions, parents and member companies, institutions, affiliates or related business entities and any and all of their past and present administrators, officers, partners, members, fiduciaries, trustees, directors, agents, representatives, shareholders, employees, board members, successors and assigns (hereinafter collectively referred to as "Releasees"), jointly and individually, from any and all actions, causes of action, grievances, arbitrations, obligations, liabilities, judgments, suits, debts, attorneys' fees, costs, sums of money, wages, bonuses, benefits of any type, accounts, reckonings, bonds, bills, specialties, covenants, contracts, controversies, agreements, promises, variances, trespasses, damages, extents, executions, claims and demands whatsoever in law, or in equity, which Employee, Employee's heirs, executors, administrators, successors and assigns, ever had, now have or hereafter can, shall or may have for, upon or by reason of any matter, cause or thing whatsoever from the beginning of time to the date Employee signs this Agreement.

ii. The foregoing release covers, without limitation, any claims of discrimination on the basis of pregnancy, race, color, sex, sexual orientation, disability, handicap, religion, creed, national origin, ancestry, age (including, without limitation, any rights or claims under the Age Discrimination Employment Act of 1967 or the Older Worker Benefits Protection Act), citizenship, ethnic characteristics, sexual or affectional preference or marital status and also includes, no matter how denominated

or described, any claims of discrimination, retaliation, harassment or interference under any federal, state or local law, rule, regulation, collective bargaining agreement, or executive order including, without limitation, any rights or claims under Title VII of the Civil Rights Act of 1964; the Genetic Information Non- Discrimination Act; the Civil Rights Acts of 1866 and 1991; 42 U.S.C. § 1981; the Equal Pay Act of 1963; the Employee Retirement Income Security Act of 1974; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Family and Medical Leave Act of 1993; the California Fair Employment & Housing Act, those portions of the California Labor Code waivable by law, the California Constitution, and all other federal, state and local laws (whether statutory, regulatory or decisional) including, but not limited to, and any claims of conversion, failure to return property, failure to pay wages, wrongful discharge or termination, interference with contract, breach of covenant, breach of contract, violation of a collective bargaining agreement, whether written or oral, express or implied, breach of promise, public policy, negligence, retaliation, defamation, defamation of character, defamation of employment records, impairment of economic opportunity, loss of business opportunity, fraud, deceit, misrepresentation, whistle-blower activities, perceived disability, history of disability and payment of wages or benefits of any type, as well as any claims for attorneys' fees or costs.

It is the intention of the Parties in executing this Agreement that it shall be a general release and shall be effective as a bar to each and every matter released herein and that, should any proceeding be instituted with respect to the matters released herein, this Agreement shall be deemed in full and complete accord, satisfaction and settlement of any such released matter and sufficient basis for dismissal. In furtherance of this intention, Employee hereby expressly waives any and all rights and benefits conferred upon Employee by the provisions of section 1542 of the California Civil Code, which provides:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

Employee agrees that Employee understands and Employee acknowledges the significance and the consequences of such a release, as well as the specific waiver of section 1542. This means that, should Employee discover any facts different from what Employee understood at the time Employee signed this Agreement, Employee will still be barred from making any claims against any of the Releasees.

iii. Except as expressly provided herein, Employee acknowledges and agrees that, by signing this Agreement, Employee is surrendering and giving up any right Employee has or may have, without limiting the generality of any other provision herein, to assert any claim for individual relief or damages against or involving Employer or the Releasees arising from or in any way relating to Employee's employment with Employer or the termination thereof, or to permit Employee to become and remain a member of any class seeking individual relief or damages against Employer or the Releasees arising from or in any way relating to Employee's employment with Employer or the termination thereof. Nothing herein, however, shall prevent Employee from filing a charge with or participating in any investigation or proceeding conducted by the Equal Employment Opportunity Commission or a state or local fair employment practices agency; provided, however, that Employee further agrees and understands that Employee has waived Employee's right to recover monetary damages or other relief personal to employees in any such charge, complaint, grievance or lawsuit filed by Employee or on Employee's behalf arising from, or in any way relating to, Employee's employment with Employer or the termination thereof, to the maximum extent permitted by applicable law. This release shall not apply to any claims which may not be released pursuant to applicable law and shall not apply to (1) Employee's Equity Rights and rights to enforce the Employment Agreement with respect to any claims with respect to payments and benefits under Sections 6.1(a), (d), and (f) of the Employment Agreement (and any payments and benefits under Section6.5 of the Employment Agreement in the event that a termination occurs within twelve (12) months following a change in control), with respect to Severance and rights under Section 8.7 of the Employment Agreement, and (2) any rights in the nature of indemnification , advancement of expense reimbursement or entitlement to insurance coverage, which the Employee may have with respect to claims against the Employee relating to or arising out of his employment with, or other provision of services to, the Company Entities.

iv. Notwithstanding anything herein or in any other agreement with or policy of the Employer to which Employee was or is subject, nothing herein or therein shall (A) prohibit Employee from making reports of possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934, as amended, or Section 806 of the Sarbanes-Oxley Act of 2002, or of any other whistleblower protection provisions of state or federal law or regulation, or (B) require Employee to comply with any notification or prior approval requirement with respect to any reporting described in clause (A); provided, however, that Employee is not authorized to disclose communications with counsel that were made for the purpose of receiving legal advice or that contain legal advice or that are protected by the attorney work product or similar privilege. Furthermore, Employee shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made(1) in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney, in each case, solely for the purpose of reporting or investigating a suspected violation of law or (2) in a complaint or other document filed in a lawsuit or proceeding, if such filings are made under seal.

(b) *Covenant Not to Sue*. Additionally, Employee agrees not sue, commence, assert, bring or file in any court or other tribunal, in any jurisdiction, any suit, action, litigation, complaint, cross-complaint, counterclaim, third-party complaint, petition or other pleading or proceeding, or otherwise seek affirmative relief against any Releasees on account of any claim released pursuant to this Agreement. Employee represents that Employee has no charges, complaints, grievances or any other claims or requests for relief pending against Employer or the Releasees (as defined above) with the Equal Employment Opportunity Commission or any other federal, state or local administrative or other judicial tribunal and has no charges, complaints, grievances or any other claims regarding allegations of sexual harassment or sexual misconduct against the Employer.

(c) *Consideration*. The Employee acknowledges the Severance is in addition to anything of value to which the Employee already is entitled from the Employer and its affiliates and constitutes good and valuable additional consideration for this Agreement.

3. Acknowledgement of Restrictive Covenants. Employee acknowledges that Employee remains bound by his obligations pursuant to Article 8 of the Employment Agreement.

4. No Admission of Liability. Employee agrees and acknowledges that nothing contained in this Agreement, nor the fact that Employee has been or will be paid any remuneration under it, shall be construed, considered or deemed to be an admission of liability or wrongdoing by either Employer or any of the Releasees. Employer and the Releasees deny committing any wrongdoing or violating any legal duty with respect to the Employee's employment or the termination of Employee's employment from Employer. The terms of this Agreement, including all facts, circumstances, statements and documents, shall not be admissible or submitted as evidence in any litigation, in any forum, for any purpose, other than to secure enforcement of the terms and conditions of this Agreement, or as may otherwise be required by law.

5. Knowing and Voluntary Waiver; Acknowledgements.

(a) The Employee acknowledges that, by the Employee's free and voluntary act of signing below, the Employee agrees to all of the terms of this Agreement and intends to be legally bound thereby. By signing this Agreement, Employee hereby acknowledges and agrees that:

i. Employee has been afforded a reasonable and sufficient period of time to review this Agreement, for deliberation thereon and for negotiation of the terms thereof, and Employee is hereby specifically urged and advised by Employer to consult with an attorney, legal counsel or a representative of Employee's choice before signing it;

ii. Employee has carefully read and understands the terms of this Agreement, all of which have been fully explained to Employee;

iii. Employee has signed this Agreement freely and voluntarily and without duress or coercion and with full knowledge of its significance and consequences and of the rights relinquished, surrendered, released and discharged hereunder;

iv. The only consideration for signing this Agreement are the terms stated herein and no other promise, agreement or representation of any kind has been made to Employee by any person or entity whatsoever to cause Employee to sign this Agreement;

v. Employee acknowledges that Employee has been informed that Employee has the right to consider this Agreement for a period of at least 21 days prior to entering into this Agreement. Employee expressly acknowledges that Employee has taken sufficient time to consider this Agreement before signing it;

vi. Employee expressly acknowledges that, if any changes – whether material or immaterial – are or were made to this Agreement after Employee's receipt for review, such changes do not commence a new 21 day period for consideration; and

vii. Employee acknowledges that this Agreement does not waive rights or claims that may arise after the date this Agreement is signed.

(b) *Effective Date*. This Agreement will become effective, enforceable and irrevocable on the eighth day after the date on which it is executed by the Employee (the "Effective Date"), provided that the Parties acknowledge and agree that this Agreement shall be null and void if executed prior to the Termination Date. During the seven-day period prior to the Effective Date, the Employee may revoke Employee's agreement to accept the terms hereof by indicating in writing to the Employer his or her intention to revoke. If the Employee exercises Employee's right to revoke hereunder, Employee shall forfeit Employee's right to receive any Severance Payments.

6. Miscellaneous.

(a) *Non-Disclosure*. Employee acknowledges and agrees that Employee will not disclose the terms of this Agreement to anyone except for Employee's spouse, tax advisor and/or attorney, and only then after having received assurances that they too will honor this confidentiality provision.

(b) *Withholding*. The Employer may withhold from any amounts payable to the Employee all federal, state, city or other taxes that the Employer may reasonably determine are required to be withheld pursuant to any applicable law or regulation, (it being understood that the Employee shall be responsible for payment of all taxes in respect of the payments and benefits provided herein).

(c) *Severability*. Any provision of this Agreement (or portion thereof) which is deemed invalid, illegal or unenforceable in any jurisdiction shall, as to that jurisdiction be ineffective to the extent of such invalidity, illegality or unenforceability, without affecting in any way the remaining provisions thereof in such jurisdiction or rendering that or any other provisions of this Agreement invalid, illegal, or unenforceable in any other jurisdiction. If any covenant should be deemed invalid, illegal or unenforceable because its scope is considered excessive, such covenant shall be modified so that the scope of the covenant is reduced only to the minimum extent necessary to render the modified covenant valid, legal and enforceable. No waiver of any provision or violation of this Agreement by the Employer shall be implied by the Employer's forbearance or failure to take action.

(d) *Notices*. All notices given hereunder shall be in writing and shall be sent by registered or certified mail, return receipt requested, or a national overnight courier service capable of providing delivery confirmation, or by hand-delivery, or by facsimile transmission with confirmed receipt, and, if intended for the Employer, shall be addressed to it at:, Attn: General Counsel and if intended for the Employee, shall be addressed to Employee at the address on file at Employer. Each such notice shall be deemed to be given on the date received at the address of the addressee or upon refusal to accept delivery.

(e) *Entire Agreement*. This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior agreements relating thereto whether written or oral.

(f) *Execution*. This Agreement may be executed in two or more facsimiled counterparts, each of which shall be equivalent to an original, but which collectively shall constitute one Agreement.

(g) *Modification; Successors and Assigns*. This Agreement may not be modified or amended, nor may any rights under it be waived, except in a writing signed and agreed to by the Parties. This Agreement shall be binding upon, inure to the benefit of and be enforceable by the Parties and their respective successors, assigns, legal representatives, executors, administrators and heirs, provided that Employee may not assign his obligations under this Agreement. Employee acknowledges and agree that the Releasees are express third party beneficiaries of this Agreement.

7. Governing Law

(a) *Governing Law*. This Agreement shall be governed by and construed in accordance with the laws of the State of California without giving effect to the rules of conflicts of law.

(b) *Arbitration*. Any dispute, claim or controversy arising under or in connection with this Agreement or Section 13.8 of the Employment Agreement is incorporated herein in its entirety mutatis mutandis.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Agreement on the date first written above.

Unicycive Therapeutics Inc.

By:
Title:

Shalabh Gupta

EXHIBIT C

[*Indemnification Agreement*]

Exhibit 10.8

EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement"), dated March 22, 2021, is by and among Unicycive Therapeutics Inc., a Delaware corporation (the "Company"), and Pramod Gupta (the "Executive").

WHEREAS, the Company desires to employ Executive, and Executive desires to be employed by, the Company, in each case effective as of March 22, 2021 (the "Effective Date");

WHEREAS, in connection with the foregoing, Executive shall be required to perform Executive's duties and obligations hereunder on behalf of the Company, as appropriate, and such duties and obligations shall be enforceable by the Company;

WHEREAS, this Agreement supersedes any and all prior employment agreements or similar agreements by and between Executive and the Company;

NOW, THEREFORE, in consideration of such employment and the mutual covenants and promises herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and Executive agree that the above recitals are hereby incorporated by reference into this Agreement and are binding upon the parties hereto and agree as follows:

1. Employment. The Company hereby agrees to employ Executive, and Executive hereby agrees to be employed with the Company, upon the terms and conditions contained in this Agreement. Unless earlier terminated by either party in accordance with Section 5, Executive's employment with the Company shall continue for an initial term commencing on the Effective Date and continuing until the third (3rd) anniversary of the Effective Date (the "Initial Term") and thereafter shall automatically renew for successive one year terms (each a "Renewal Term") unless either party provides written notice of non-renewal to the other party at least sixty (60) days prior to the last day of the then-current term (such Initial Term and subsequent Renewal Term(s) or portions thereof occurring prior to termination, collectively the "Employment Period").

2. Duties.

2.1 During the Employment Period, Executive shall serve on a full-time basis and perform services in a capacity and in a manner consistent with Executive's position for the Company. Executive shall have the title of Executive Vice President, Pharmaceutical and Business Operations of the Company and shall have such duties, authorities and responsibilities as are consistent with such position, as the Board of Directors of the Company (the "Company Board") may designate from time to time. Executive will report directly to the Chief Executive Officer of the Company. During the Employment Period, the Company Board shall recommend to its shareholders that Executive be elected as a member of the Company Board and, if so elected, Executive shall serve for no additional consideration as a member of the Company Board. Executive agrees that during Executive's employment with the Company, Executive will devote Executive's full business time, attention, skill and best efforts to the performance of Executive's employment duties and Executive is not to engage in any other business or occupation without approval of the Company Board. Notwithstanding the foregoing, Executive may (i) serve as a director or advisor of one (1) for-profit company without the prior approval of the Company Board; (ii) perform and participate in charitable, civic, educational, professional, community and industry affairs and other related activities; and (iii) manage Executive's personal investments, provided, however, that such activities do not materially interfere, individually or in the aggregate with the performance of Executive's duties hereunder.

3. Location Of Employment. Executive shall work remotely until such time as Executive and the Company mutually agree that Executive will work from the Company offices..

4. Compensation.

4.1 Base Salary. In consideration of all services rendered by Executive under this Agreement, the Company shall pay Executive a base salary (the "Base Salary") at an annual rate of $450,000 during the Employment Period. The Base Salary shall be paid in such installments and at such times as the Company pays its regularly salaried employees, but no less often than once per month.

4.2 Annual Discretionary Bonus. During each fiscal year of the Executive's employment with the Company (commencing with the 2021 fiscal year), Executive will be eligible to receive an annual discretionary bonus ("Cash Bonus"). Executive's target Cash Bonus shall be equal to 50% of Base Salary (the "Target Bonus"). The Cash Bonus amount will be based upon achievement of Company and individual performance targets established by the Company Board, in its sole and absolute discretion, for the fiscal year to which the bonus relates. The payment of any Cash Bonus described herein will be made at the same time annual bonuses are generally paid to other senior executives of the Company (generally the first regular payroll date following the Company Board's certification of achievement of applicable performance targets). If Executive is eligible to receive a Cash Bonus, such bonus will not be deemed to be fully "earned" unless Executive is (i) employed by the Company and in good standing on the last day of the fiscal year to which the Cash Bonus relates, and (ii) has not given notice of Executive's intention to resign Executive's employment as of, or prior to, the date the Company pays the applicable Cash Bonus. The Cash Bonus shall be paid to Executive no later than March 15th of the year following the year for which the bonus is payable.

4.3 Equity Award. Executive will, on or as soon as reasonably practicable after the date of an initial public offering of the Company (the "IPO Date"), be granted an equity-based compensation award ("Award") in such amounts and subject to such terms and conditions that are consistent with, and no less favorable to Executive than, the terms and conditions set forth in Exhibit A attached hereto. Upon termination of Executive's employment, the treatment of any portion of outstanding Award shall be determined in accordance with the terms of any agreements governing such Award (" Award Agreement "). Executive shall remain eligible to receive additional equity-based compensation awards as the Company may grant from time to time.

4.4 Vacation. During the Employment Period, Executive shall be entitled to vacation benefits consistent with Company policy, as may be in effect from time to time, except to the extent such policy is inconsistent with this Agreement.

4.5 Benefits. During the Employment Period, Executive shall be entitled to participate in any benefit plans offered by the Company as in effect from time to time (collectively, "Benefit Plans") on the same basis as those generally made available to other senior employees of the Company, to the extent Executive may be eligible to do so under the terms of any such Benefit Plan. Executive acknowledges and agrees that any such Benefit Plans may be terminated or amended from time to time by the Company in its sole discretion. During the Employment Period, the Company shall provide Executive with (i) life insurance coverage (equal to at least two (2) times Executive's Base Salary), and (ii) disability insurance coverage. The Company will cover Executive under directors' and officers' liability insurance, with Executive as a named insured, during Executive's employment, to the same general extent as other executive officers of the Company.

5. Termination. Executive's employment hereunder may be terminated as follows:

5.1 Automatically in the event of the death of Executive;

5.2 At the option of the Company, by written notice to Executive or Executive's personal representative in the event of the Disability of Executive. As used herein, the term "Disability" shall mean a determination by an independent competent medical authority (mutually agreed upon by Executive and the Company) that Executive is unable to perform Executive's duties under this Agreement with or without reasonable accommodation, for a period of 120 consecutive days or 180 days in any 365 day period. If there is a question as to the existence of Executive's Disability as to which Executive and the Company cannot agree, same shall be determined in writing by a qualified independent medical authority mutually acceptable to Executive and the Company. If the parties hereto cannot agree as to a qualified independent physician, each of the Executive, on the one hand, and the Company, on the other, shall appoint such a physician and those two physicians shall select a third who shall make such determination in writing. The determination of Disability made in writing to the Company and Executive shall be final and conclusive for all purposes of this Agreement. Executive shall fully cooperate in connection with the determination of whether Disability exists.

5.3 At the option of the Company for Cause (as defined in Section 6.5), on prior written notice to Executive (subject to any cure period described in Section 6.5);

5.4 At the option of the Company without Cause, on thirty (30) days' prior written notice to Executive;

5.5 At the option of Executive (a) for Good Reason (in accordance with the definition in Section 6.5) or (b) for any or no reason other than Good Reason on thirty (30) days' prior written notice to the Company (which the Company may, in its sole discretion, make effective as a resignation earlier than the termination date provided in such notice and further provided that if Executive unilaterally resigns Executive's employment before the end of such requisite notice period then such resignation shall be treated for purposes of this Agreement as a termination under Section 5.4); or

5.6 As of the last day of the Initial Term or the then-current Renewal Term if either Executive or the Company elects not to renew the Agreement in accordance with and subject to the notice provisions set forth in Section 1.

6. Severance Payments.

6.1 Non-Renewal by the Company, Termination by the Company Without Cause or Termination by Executive for Good Reason. If Executive's employment is terminated by the Company without Cause (and not due to death or Disability), by Executive for Good Reason or as the result of the Company's decision not to renew the Agreement in accordance with Section 1, subject to Section 6.7 hereof, Executive shall be entitled to:

(a) within thirty (30) days following such termination, or sooner as may be required by law, payment of Executive's accrued and unpaid Base Salary and reimbursement of expenses under Section 7 hereof in each case accrued through the date of termination;

(b) subject to Section 13.7(b) hereof, an amount in cash equal to the sum of (i) twelve (12) months of Executive's Base Salary as in effect as of Executive's last day of employment and (ii) Executive's Target Bonus as in effect as of Executive's last day of employment (but in no event less than Executive's bonus paid in the prior year), which sum of (i) and (ii) shall be payable in substantially equal installments (the "Severance Amount") at the same time Base Salary would be paid over the twelve (12) month period (the "Severance Period") following termination; provided, however, if the Executive's review and revocation period for the release of claims required pursuant to Section 6.7 hereof spans two of Executive's taxable years, the first payment shall be made on the first regularly scheduled payroll date of the later taxable year following the effective date of such release of claims and shall include all amounts accrued prior thereto;

(c) if Executive is eligible for and elects to enroll in "COBRA" type continuation coverage of Executive's health benefits under the Company's group health plan, for the Severance Period ("COBRA Payment Period") the Company will pay Executive on a monthly basis a taxable amount equal to the full monthly premium (just the Company portion) for the corresponding active employee coverage type (e.g., single, single plus one, family) under the Company's group health plan that was in effect for Executive on the termination date, less applicable taxes and withholdings; provided, that the Company's obligation to make these monthly taxable COBRA premium payments to Executive hereunder shall cease on the earlier of: (i) the date on which Executive first becomes eligible for coverage under any group health plan made available by another employer (and Executive shall notify the Company in writing promptly, but within 10 days, after becoming eligible for any such benefits); and (ii) the date on which Executive's COBRA continuation coverage under the Company's group health plan ends on account of Executive's election to terminate such coverage; notwithstanding the foregoing, if the Company determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Internal Revenue Code of 1986, as amended (the "Code") or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums; the Company, in its sole discretion, may elect to instead pay Executive on the first day of each month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings (such amount, the "Special Severance Payment"), for the remainder of the COBRA Payment Period (Executive may, but is not obligated to, use such Special Severance Payment toward the cost of COBRA premiums); notwithstanding the foregoing, if for any reason Executive is ineligible for, or does not elect to enroll in "COBRA" type continuation coverage of Executive's health benefits under the Company's group health plan, the Company will pay Executive a lump sum equal to the aggregate payments the Company would have paid Executive on a monthly basis pursuant to the above provisions;

(d) a lump sum payment equal to the amount of any Cash Bonus earned with respect to a fiscal year ending prior to the date of such termination but unpaid as of such date, payable at the same time in the year of termination as such payment would be made if Executive continued to be employed by the Company, but in no event later than 73 days following the end of the fiscal year in which the termination occurs;

(e) a lump sum payment equal to the amount of Cash Bonus that was accrued for the year in which Executive's employment ends based upon the good faith determination of the Company Board in accordance with the Company's normal practices as of the last day of the calendar month during which Executive's termination became effective (it being understood that the Company will accrue the Cash Bonus on a monthly basis), payable no later than 73 days after the termination date;

(f) all other accrued or vested amounts or benefits due to Executive in accordance with this Agreement, the Company's benefit plans, programs or policies (other than severance), and

(g) subject to Executive's compliance with the restrictive covenants set forth in Section 8 hereof, the portion of any then outstanding and unvested portion of any time-vesting equity award granted to Executive by the Company that would vest on the next vesting date shall automatically vest upon Executive's termination date, multiplied by a fraction, where the numerator is the number of days Executive 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.

6.2 Termination due to Executive's Death or Disability. Upon the termination of Executive's employment due to Executive's death or Disability pursuant to Section 5.1 and Section 5.2 respectively, Executive or Executive's legal representatives shall be entitled to receive (i) the acceleration and vesting in full of any then outstanding and unvested portion of any time-vesting equity award granted to Executive by the Company; and (ii) the payments and benefits described under Sections 6.1(a), (d), (e) and (f).

6.3 Termination due to Non-Renewal by Executive or Termination by Executive without Good Reason. Upon the termination of Executive's employment due to the non-renewal by Executive or termination by Executive without Good Reason, Executive shall be entitled to receive only the payments and benefits described in Sections 6.1(a), (d), and (f), and the treatment of Executive's Award in accordance with the Award Agreement.

6.4 Termination by the Company for Cause. Upon the termination of Executive's employment by the Company for Cause pursuant to Section 5.3, Executive shall be entitled to receive only the payments and benefits described in Sections 6.1(a) and (f), and the treatment of Executive's Award in accordance with the Award Agreement.

6.5 Termination Following Change in Control. If Executive's employment is terminated by the Company without Cause or by Executive for Good Reason within twelve (12) months following a Change in Control, Executive shall be entitled to receive the following:

(i) the acceleration and vesting in full of any then outstanding and unvested portion of any time- vesting equity award granted to Executive by the Company; and (ii) the benefits described Sections 6.1(a), (b), (c), (d), (e) and (f).

6.6 Definitions.

(a) Cause. For purposes of this Agreement, "Cause" shall mean:

(i) Executive's continued failure or refusal to follow the lawful directives of the Company Board after being given written notice and thirty (30) days to remedy such failures or refusals;

(ii) Executive's willful misconduct, gross negligence, act of material dishonesty in connection with Executive's employment;

(iii) Executive's indictment for, or a plea of guilty or no contest to, any felony or any other criminal offence involving serious moral turpitude;

(iv) Executive's violation of any material written policies of the Company or its affiliates of which Executive has received written notice and which violation is, in each case, if curable, is not cured within thirty (30) days of written notice from the Company;

(v) Executive's breach of any non-solicitation or non-competition obligations to the Company or its affiliates, including, without limitation, those set forth in Sections 8.1 and 8.2 of this Agreement or Executive's willful, grossly negligent, or reckless breach of any confidentiality obligations to the Company or its affiliates, including, without limitation, those set forth in Section 8.3 of this Agreement;

(vi) material breach by Executive of any of the provisions of this Agreement or any other agreement between the Company and its affiliates on the one hand and Executive on the other hand, which (if curable) is not cured within thirty (30) days of written notice; or

(vii) as provided in Section 13.1 hereof.

(b) "Change in Control" shall have the meaning given that term in the Company's 2021 Omnibus Equity Incentive Plan.

(c) "Good Reason" shall mean, without Executive's prior written consent, (i) a material diminution in Executive's title, authority, duties or responsibilities; (ii) a material reduction in Base Salary; (iii) a material reduction in the target percentage of the Executive's Cash Bonus; (iv) the relocation of Executive's principal place of employment more than fifty (50) miles from its then current location; or (v) a breach by the Company of any material provision of this Agreement (the parties agreeing that Section 4.1 is one such material provision). Any Good Reason termination will require thirty (30) days' advanced written notice by Executive of the event giving rise to Good Reason within sixty (60) days after Executive first learns of the applicable event, and will not be effective unless the Company has not cured the Good Reason event within such thirty (30) day notice period. In order for Executive to resign for Good Reason, Executive must resign from Executive's employment within sixty (60) days after the failure of the Company to cure a Good Reason event.

(d) "Person" means any natural person, sole proprietorship, general partnership, limited partnership, limited liability company, joint venture, trust, unincorporated organization, association, corporation, governmental authority or any other organization, irrespective of whether it is a legal entity and includes any successor (by merger or otherwise) of such entity.

6.7 Conditions to Payment. All payments and benefits due to Executive under this Section 6, other than the payments due to Executive under Sections 6.1(a), (d), and (f) or which are otherwise required by law (all other payments under Section 6, "Severance"), shall only be payable if Executive (or Executive's beneficiary or estate) delivers to the Company and does not revoke (under the terms of applicable law) a general release of all claims substantially in the form attached hereto as Exhibit B. Such general release shall be executed and delivered (and no longer subject to revocation) within fifty-five (55) days following termination. Failure to timely execute and return such release or revocation thereof shall be a waiver by Executive of Executive's right to receive any Severance. In addition, Severance shall be conditioned on Executive's compliance with Section 8 hereof.

7. Reimbursement of Expenses. The Company shall reimburse Executive for reasonable and necessary expenses actually incurred by Executive directly in connection with the business and affairs of the Company and the performance of Executive's duties hereunder, in each case subject to appropriate substantiation and itemization of such expenses in accordance with the guidelines and limitations established by the Company from time to time.

8. Restrictions on Activities of Executive.

8.1 Non-Competition. During employment and for the one (1) year period commencing on the date Executive's employment with the Company pursuant to this Agreement ends (except in the event Executive's employment ends due to Executive's Disability) (the "Restriction Period"), Executive covenants and agrees that Executive shall not directly or indirectly (whether for compensation or otherwise) own or hold any interest in, manage, operate, control, consult with, render services for, or in any manner participate in, any Competitive Business, in each case, either as a general or limited partner, proprietor, shareholder, officer, director, agent, employee, consultant, trustee, affiliate or otherwise. The Company may opt to extend the Restriction Period for up to an additional one (1) year period, provided that in such case Company shall also increase the Severance Amount and the Severance Period by one- twelfth (1/12) for each month that the Restricted Period is lengthened. For clarification, if Executive is not otherwise

entitled to a Severance Amount, the Company shall pay Executive an amount equal to one-twelfth (1/12) of Executive's Base Salary for each month the Restricted Period is lengthened. Nothing herein shall prohibit Executive from being a passive owner of not more than one percent (1%) of the outstanding securities of any publicly traded company engaged in a Competitive Business. For purposes of this Agreement, "Competitive Business" shall mean (x) the development of novel treatments for unmet medical conditions, including but not limited to the development of drugs for (A) controlling hyperphosphatemia in patients with Chronic Kidney Disease and (B) the treatment of patients with Acute Kidney Injury, (y) the pursuit of other drugs for in-licensing into the Company's pipeline, and (z) any other business that the Company is conducting or is considering conducting by virtue of management executives having held internal strategy discussions and/or discussions with members of the Company Board regarding the same prior to the time Executive's employment is terminated, and of which Executive is aware. Despite the foregoing, nothing contained in this Agreement shall be construed to prevent Executive from being employed by or providing services to Globavir Biosciences, Inc., a Delaware corporation.

8.2 Non-Solicitation. Executive covenants and agrees that, except in connection with the performance of Executive's duties to the Company, during the Restriction Period, Executive shall not directly or indirectly (i) influence or attempt to influence or solicit any employees or independent contractors of the Company or any of its affiliates to restrict, reduce, sever or otherwise alter their relationship with the Company or such affiliates, (ii) hire any employees or independent contractors of the Company or any of its affiliates, (iii) solicit or induce, or attempt to solicit or induce, any Person that is then a client or customer of the Company, or any of its affiliates to cease being a client or customer of the Company or any of its affiliates or to divert all or any part of such Person's business from the Company or any of its affiliates, or (iv) assist any other Person in any way to do, or attempt to do, anything prohibited by Sections 8.2(i), (ii), or (iii); provided, however, that the foregoing restrictions shall not include (A) general solicitations of employment or hiring of persons responding to general solicitations of employment (including general advertising via periodicals, the Internet and other media) not specifically directed towards employees of the Company or its affiliates, or (B) serving as a third-party reference for any employee or independent contractor or providing advice to any employees.

8.3 Confidentiality. Executive shall not, during the Employment Period or at any time thereafter directly or indirectly, disclose, reveal, divulge or communicate to any Person other than authorized officers, directors and employees of the Company or use or otherwise exploit for Executive's own benefit or for the benefit of anyone other than the Company, any Confidential Information (as defined below). "Confidential Information" means any information with respect to the Company or any of its affiliates, including methods of operation, customer lists, products, prices, fees, costs, technology, formulas, inventions, trade secrets, know-how, software, marketing methods, plans, personnel, suppliers, competitors, markets or other specialized information or proprietary matters; provided, that, there shall be no obligation hereunder with respect to, information that (i) is generally available to the public on the Effective Date, (ii) becomes generally available to the public other than as a result of a disclosure not otherwise permissible hereunder, or (iii) is required to be disclosed by law, court order or other legal or regulatory process and Executive gives the Company prompt written notice and the opportunity to seek a protective order. For the avoidance of doubt, Executive understands that pursuant to the federal Defend Trade Secrets Act of 2016, Executive shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Nothing contained in this Agreement shall limit Executive's ability to communicate with any federal, state or local governmental agency or commission, including to provide documents or other information, without notice to the Company. Further, nothing in this Agreement shall be deemed to preclude Executive from testifying truthfully under oath if Executive is required or compelled by law to testify in any judicial action or before any government authority or agency or from making any other legally-required truthful statements or disclosures.

8.4 Assignment of Inventions.

(a) Executive agrees that during employment with the Company, any and all inventions, discoveries, innovations, writings, domain names, improvements, trade secrets, designs, drawings, formulas, business processes, secret processes and know-how, whether or not patentable or a copyright or trademark, which Executive may create, conceive, develop or make, either alone or in conjunction with others and related or in any way connected with the Company's strategic plans, products, processes or apparatus or the business (collectively, "Inventions"), shall be fully and promptly disclosed to the Company and shall be the sole and exclusive property of the Company as against Executive or any of Executive's assignees. Regardless of the status of Executive's employment by the Company, Executive and Executive's heirs, assigns and representatives shall promptly assign to the Company any and all right, title and interest in and to such Inventions made during employment with the Company.

(b) Whether during or after the Employment Period, Executive further agrees to execute and acknowledge all papers and to do, at the Company's expense, any and all other things necessary for or incident to the applying for, obtaining and maintaining of such letters patent, copyrights, trademarks or other intellectual property rights, as the case may be, and to execute, on request, all papers necessary to assign and transfer such Inventions, copyrights, patents, patent applications and other intellectual property rights to the Company and its successors and assigns. In the event that the Company is unable, after reasonable efforts and, in any event, after ten (10) business days, to secure Executive's signature on a written assignment to the Company, of any application for letters patent, trademark registration or to any common law or statutory copyright or other property right therein, whether because of Executive's physical or mental incapacity, or for any other reason whatsoever, Executive irrevocably designates and appoints the Secretary of the Company as Executive's attorney-in-fact to act on Executive's behalf to execute and file any such applications and to do all lawfully permitted acts to further the prosecution or issuance of such assignments, letters patent, copyright or trademark.

8.5 Return of Company Property. Within ten (10) days following the date of any termination of Executive's employment, Executive or Executive's personal representative shall return all property of the Company and its affiliates in Executive's possession, including but not limited to all Company-owned computer equipment (hardware and software), smart phones, facsimile machines, tablet computers and other communication devices, credit cards, office keys, security access cards, badges, identification cards and all copies (including drafts) of any documentation or information (however stored) relating to the business of the Company and its affiliates, its customers and clients or its prospective customers and clients. Anything to the contrary notwithstanding, Executive shall be entitled to retain (i) personal papers and other materials of a personal nature, provided that such papers or materials do not include Confidential Information, (ii) information showing Executive's compensation or relating to reimbursement of expenses, and (iii) copies of plans, programs and agreements relating to Executive's employment, or termination thereof, with the Company which Executive received in Executive's capacity as a participant.

8.6 Resignation as an Officer and Director. Upon any termination of Executive's employment, Executive shall be deemed to have resigned, to the extent applicable, if any, as an officer of the Company and any of its affiliates, a member of the Company Board, or the board of directors or equivalent of any of the Company's affiliates and as a fiduciary of any Company or Affiliate benefit plan. On or immediately following the date of any termination of Executive's employment, Executive shall confirm the foregoing by submitting to the Company in writing a confirmation of Executive's resignation(s).

8.7 Cooperation. During the Employment Period and for six years thereafter, Executive shall give Executive's assistance and cooperation, upon reasonable advance notice, in any litigation matter relating to Executive's position with the Company and its affiliates, or Executive's knowledge as a result thereof as the Company may reasonably request, including Executive's attendance and truthful testimony where deemed appropriate by the Company, with respect to any investigation or the Company's (or an affiliate's) defense or prosecution of any existing or future claims or litigations or other proceeding relating to matters in which Executive was involved or had knowledge by virtue of Executive's employment with the Company, in all cases on schedules that are reasonably consistent with Executive's other permitted activities and commitments. The Company agrees to reimburse Executive for any costs Executive incurs in connection with complying with this Section, including Executive's reasonable attorney's fees. If Executive's compliance with this Section requires Executive to expend more than ten (10) hours (any time in excess of ten (10) hours, "Excess Time") in any quarter of a

calendar year, the Company agrees to compensate Executive for such Excess Time at an hourly rate that is equal to the prorata rate the Executive earned while under employment with the Company.

8.8 Non-Disparagement. During Executive's employment with the Company, and at all times thereafter, (i) Executive shall not make either orally or in writing any derogatory or disparaging statement with regard to the Company, any of its businesses, products, services or practices or any of its managers, directors, officers, employees or agents, and (ii) the Company shall direct the members of the Company Board and its senior executives not to make either orally or in writing any derogatory or disparaging statement with regard to the Executive, provided that nothing in this Section 8.8 shall prevent either party from giving a deposition, responding to any subpoena or other lawful request for information or documentation made in the course of a legal or administrative proceeding or testifying in court or in any other legal proceeding. In addition, Executive agrees not to, without Company's prior written consent, communicate, directly or indirectly, with the press or other media, concerning the past or present employees or businesses of the Company.

8.9 Survival. This Section 8 shall survive any termination or expiration of this Agreement or employment of Executive.

9. Remedies. It is specifically understood and agreed that any breach of the provisions of Section 8 of this Agreement is likely to result in irreparable injury to the Company and that the remedy at law alone will be an inadequate remedy for such breach, and that in addition to any other remedy it may have in the event of a breach or threatened breach of Section 8 above, the Company shall be entitled to enforce the specific performance of this Agreement by Executive and to seek both temporary and permanent injunctive relief (to the extent permitted by law) without bond and without liability should such relief be denied, modified or violated.

10. Blue Pencil. Each of the rights enumerated in this Agreement shall be independent of the others and shall be in addition to and not in lieu of any other rights and remedies available to the Company or any of its direct or indirect subsidiaries at law or in equity. If any of the provisions of this Agreement or any part of any of them is hereafter construed or adjudicated to be invalid or unenforceable because of the duration of such provisions or the area or scope covered thereby, Executive agrees that the court making such determination shall have the power to reduce the duration, scope and/or area of such provisions to the maximum and/or broadest duration, scope and/or area permissible by law, and in its reduced form said provision shall then be enforceable.

11. Severable Provisions. The provisions of this Agreement are severable and the invalidity of any one or more provisions shall not affect the validity of any other provision. In the event that a court of competent jurisdiction shall determine that any provision of this Agreement or the application thereof is unenforceable in whole or in part because of the duration or scope thereof, the parties hereto agree that said court in making such determination shall have the power to reduce the duration and scope of such provision to the extent necessary to make it enforceable, and that the Agreement in its reduced form shall be valid and enforceable to the full extent permitted by law.

12. Notices. All notices hereunder, to be effective, shall be in writing and shall be deemed effective when delivered by hand or mailed by (a) certified mail, postage and fees prepaid, or (b) nationally recognized overnight express mail service, as follows:

If to the Company:

Unicycive Therapeutics Inc.
5150 El Camino Real, Suite #A-32 Los Altos, CA 94022
Attention: Shalabh Gupta, MD
with a copy (which shall not constitute notice) to: Sheppard, Mullin, Richter & Hampton LLP
30 Rockefeller Plaza
New York, New York 10112
Attention: Jeffrey Fessler, Esq. Facsimile: 917.438.6133
Telephone: 212.634.3067
E-mail: jfessler@sheppardmullin.com If to Executive:
The last address shown on records of the Company with a copy (which shall not constitute notice) to:

Ethan D. Feffer, Esq. Feffer Legal Advisory
895 Dove Street, Suite 300 Newport Beach, CA 92660 Telephone: 949.533.7645
E-mail: efeffer@edfadvisory.com

or to such other address as a party may notify the other pursuant to a notice given in accordance with this Section 12.

13. Miscellaneous.

13.1 Executive Representation. Executive hereby represents to the Company that Executive's execution and delivery of this Agreement and Executive's performance of Executive's duties hereunder shall not constitute a breach of, or otherwise contravene, or be prevented, interfered with or hindered by, the terms of any employment agreement or other agreement or policy to which Executive is a party or otherwise bound, and further that Executive is not subject to any limitation on Executive's activities on behalf of the Company as a result of agreements into which Executive has entered except for obligations of confidentiality with former employers. To the extent this representation and warranty is not true and accurate, it shall be treated as a Cause event and the Company may terminate Executive for Cause or not permit Executive to commence employment.

13.2 No Mitigation or Offset. In the event of any termination of Executive's employment hereunder, Executive shall be under no obligation to seek other employment or otherwise mitigate the obligations of the Company under this Agreement, and there shall be no offset against amounts due Executive under this Agreement on account of future earnings by Executive.

13.3 Entire Agreement; Amendment. Except as otherwise expressly provided herein, this Agreement constitutes the entire agreement between the parties hereto with regard to the subject matter hereof, superseding all prior understandings and agreements, whether written or oral. This Agreement may not be amended or revised except by a writing signed by the parties.

13.4 Assignment and Transfer. The provisions of this Agreement shall be binding on and shall inure to the benefit of the Company and any successor in interest to the Company who acquires all or substantially all of the Company's assets. The Company may assign this Agreement to an affiliate. Neither this Agreement nor any of the rights, duties or obligations of Executive shall be assignable by Executive, nor shall any of the payments required or permitted to be made to Executive by this Agreement be encumbered, transferred or in any way anticipated, except as required by applicable law. All rights of Executive under this Agreement shall inure to the benefit of and be enforceable by Executive's personal or legal representatives, estates, executors, administrators, heirs and beneficiaries.

13.5 Waiver of Breach. A waiver by either party of any breach of any provision of this Agreement by the other party shall not operate or be construed as a waiver of any other or subsequent breach by the other party.

13.6 Withholding. The Company shall be entitled to withhold from any amounts to be paid or benefits provided to Executive hereunder any federal, state, local or foreign withholding, FICA and FUTA contributions, or other taxes, charges or deductions which it is from time to time required to withhold.

13.7 Code Section 409A.

(a) The parties agree that this Agreement shall be interpreted to comply with or be exempt from Section 409A of the Code and the regulations and guidance promulgated thereunder to the extent applicable (collectively "Code Section 409A"), and all provisions of this Agreement shall be construed in a manner consistent with the requirements for avoiding taxes or penalties under Code Section 409A. In no event whatsoever will the Company be liable for any additional tax, interest or penalties that may be imposed on Executive under Code Section 409A or any damages for failing to comply with Code Section 409A.

(b) A termination of employment shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits considered "nonqualified deferred compensation" under Code Section 409A upon or following a termination of employment unless such termination is also a "separation from service" within the meaning of Code Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment" or like terms shall mean "separation from service." If Executive is deemed on the date of termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B), then with regard to any payment or the provision of any benefit that is considered nonqualified deferred compensation under Code Section 409A payable on account of a "separation from service," such payment or benefit shall be made or provided at the date which is the earlier of (i) the expiration of the six (6)-month period measured from the date of such "separation from service" of Executive, and (ii) the date of Executive's death (the "Delay Period"). Upon the expiration of the Delay Period, all payments and benefits delayed pursuant to this Section 13.7(b) (whether they would have otherwise been payable in a single sum or in installments in the absence of such delay) shall be paid or reimbursed on the first business day following the expiration of the Delay Period to Executive in a lump sum, and any remaining payments and benefits due under this Agreement shall be paid or provided in accordance with the normal payment dates specified for them herein.

(c) With regard to any provision herein that provides for reimbursement of costs and expenses or in-kind benefits, except as permitted by Code Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits, to be provided in any other taxable year, provided, that, this clause (ii) shall not be violated with regard to expenses reimbursed under any arrangement covered by Internal Revenue Code Section 105(b) solely because such expenses are subject to a limit related to the period the arrangement is in effect and (iii) such payments shall be made on or before the last day of Executive's taxable year following the taxable year in which the expense occurred.

(d) For purposes of Code Section 409A, Executive's right to receive any installment payments pursuant to this Agreement shall be treated as a right to receive a series of separate and distinct payments. Whenever a payment under this Agreement specifies a payment period with reference to a number of days (e.g., "payment shall be made within thirty (30) days following the date of termination"), the actual date of payment within the specified period shall be within the sole discretion of the Company.

13.8 Arbitration. If any contest or dispute arises between the parties with respect to this Agreement or Executive's employment or termination thereof, other than injunctive and equitable relief with regard to Section 9 hereof, such contest or dispute shall be submitted to binding arbitration to occur in San Francisco, California before a single arbitrator in accordance with the rules and procedures of the Employment Dispute Resolution Rules of the American Arbitration Association (" AAA") then in effect. The decision of the arbitrator shall be final and binding on the parties and may be entered in any court of applicable jurisdiction. The parties shall bear their own legal fees in any arbitration.

13.9 Governing Law. This Agreement shall be construed under and enforced in accordance with the laws of the State of California, without regard to the conflicts of law provisions thereof.

13.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and shall have the same effect as if the signatures hereto and thereto were on the same instrument.

[remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the day and year first above written.

UNICYCIVE THERAPEUTICS INC.

By: /s/ Shalabh Gupta, MD
Name: Shalabh Gupta, MD
Title: President & CEO

EXECUTIVE

/s/ Pramod Gupta
Pramod Gupta

EXHIBIT A

EQUITY TERMS

Type of Award ("Award")	● An award of stock options to purchase 150,000 shares of the Company's common stock under the Company's 2021 Omnibus Equity Incentive Plan will be made to Executive on or as soon as reasonably practicable following the IPO Date. ● Award is evidenced by agreement executed by Executive and the Company.
Vesting and Exercisability of Award	● The Award shall vest in equal one-third (1/3) installments on the first, second and third anniversaries of the Date of Grant (as defined in the applicable award agreement), subject to acceleration of vesting in the circumstances set forth below. ● Unless Executive forfeits the vested portion of the Award due to a termination for Cause or a breach of restrictive covenants, the vested portion of the Award will remain exercisable for a period of twelve (12) months from the date of termination of Executive's employment.
Termination of Service for Cause, resignation with/without cause, death & disability, etc.	● In the event Executive's employment is terminated due to death or Disability, or in the event Executive's employment is terminated without Cause or Executive resigns for Good Reason within one (1) year of a Change in Control, the Award shall become fully vested.

EXHIBIT B

GENERAL RELEASE OF CLAIMS

GENERAL RELEASE and WAIVER (this "Agreement") made as of _____, by and between Pramod Gupta (the "Employee") and Unicycive Therapeutics Inc. (the "Employer," together with the Employee, the "Parties").

WHEREAS, Employee and the Employer have agreed that Employee's employment with the Company has been terminated;

WHEREAS, Employee and the Employer have previously entered into an Employment Agreement dated , 2021, as may have been amended or supplemented from time to time (the "Employment Agreement"), with any terms used, but not defined herein, having the meaning set forth in the Employment Agreement; and

WHEREAS, the Parties desire to enter into this Agreement, in satisfaction of all obligations of the Employee and the Employer in respect of Employee's employment with the Employer.

NOW, THEREFORE, in consideration of the mutual covenants set forth herein and for other good and valuable consideration, receipt of which is hereby acknowledged, the Employer and the Employee agree as follows:

1. Separation

(a) *Date of Separation.* Employee's employment with the Employer and all of its subsidiaries and affiliates will end on [DATE] (the "Termination Date"). Employee hereby acknowledges and agrees that Employee has resigned, effective as of the Termination Date, from any and all positions and titles Employee holds with the Employer and all of its affiliates (together, "Company Entities").

(b) *Severance.* In consideration for, subject to and conditioned on Employee's execution of this Agreement on or within twenty-one (21) days following the Termination Date, Employee's non-revocation thereof and compliance with such other conditions as are set forth in the Employment Agreement, Employee is eligible to receive the Severance in accordance with the terms and conditions set forth in the Employment Agreement.

(c) *Full Satisfaction.* The Employee acknowledges and agrees that, except for his equity award for__shares that are vested **("Equity Rights")** the payments and benefits under Sections 6.1(a), (d), (f) and (g) of the Employment Agreement, or under Section 6.5 of the Employment Agreement in the event that a Termination occurs within twelve (12) months following a Change in Control, and except for Severance, the Employee is not entitled to any other compensation or benefits from the Company Entities (including without limitation any severance or termination compensation or benefits under any severance plan, program, policies, practices or arrangements of any of the Company Entities).

(d) *COBRA*. Pursuant to the applicable group plan terms and conditions, Employee will cease participating in Employer's health insurance plans as of the Termination Date. If applicable, the Employer will send the Employee documentation under separate cover relating to the Employee's rights pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA").

2. General Release and Waiver

(a) *Release.*

i. In exchange for and in consideration of the promises and covenants set forth in this Agreement and the Employment Agreement, Employee irrevocably and unconditionally releases and discharges the Company Entities and each of their subsidiaries, divisions, parents and member companies, institutions, affiliates or related business entities and any and all of their past and present administrators, officers, partners, members, fiduciaries, trustees, directors, agents, representatives, shareholders, employees, board members, successors and assigns (hereinafter collectively referred to as "Releasees"), jointly and individually, from any and all actions, causes of action, grievances, arbitrations, obligations, liabilities, judgments, suits, debts, attorneys' fees, costs, sums of money, wages, bonuses, benefits of any type, accounts, reckonings, bonds, bills, specialties, covenants, contracts, controversies, agreements, promises, variances, trespasses, damages, extents, executions, claims and demands whatsoever in law, or in equity, which Employee, Employee's heirs, executors, administrators, successors and assigns, ever had, now have or hereafter can, shall or may have for, upon or by reason of any matter, cause or thing whatsoever from the beginning of time to the date Employee signs this Agreement.

ii. The foregoing release covers, without limitation, any claims of discrimination on the basis of pregnancy, race, color, sex, sexual orientation, disability, handicap, religion, creed, national origin, ancestry, age (including, without limitation, any rights or claims under the Age Discrimination Employment Act of 1967 or the Older Worker Benefits Protection Act), citizenship, ethnic characteristics, sexual or affectional preference or marital status and also includes, no matter how denominated or

described, any claims of discrimination, retaliation, harassment or interference under any federal, state or local law, rule, regulation, collective bargaining agreement, or executive order including, without limitation, any rights or claims under Title VII of the Civil Rights Act of 1964; the Genetic Information Non- Discrimination Act; the Civil Rights Acts of 1866 and 1991; 42 U.S.C. § 1981; the Equal Pay Act of 1963; the Employee Retirement Income Security Act of 1974; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990; the Family and Medical Leave Act of 1993; the California Fair Employment & Housing Act, those portions of the California Labor Code waivable by law, the California Constitution, and all other federal, state and local laws (whether statutory, regulatory or decisional) including, but not limited to, and any claims of conversion, failure to return property, failure to pay wages, wrongful discharge or termination, interference with contract, breach of covenant, breach of contract, violation of a collective bargaining agreement, whether written or oral, express or implied, breach of promise, public policy, negligence, retaliation, defamation, defamation of character, defamation of employment records, impairment of economic opportunity, loss of business opportunity, fraud, deceit, misrepresentation, whistle-blower activities, perceived disability, history of disability and payment of wages or benefits of any type, as well as any claims for attorneys' fees or costs.

iii. It is the intention of the Parties in executing this Agreement that it shall be a general release and shall be effective as a bar to each and every matter released herein and that, should any proceeding be instituted with respect to the matters released herein, this Agreement shall be deemed in full and complete accord, satisfaction and settlement of any such released matter and sufficient basis for dismissal. In furtherance of this intention, Employee hereby expressly waives any and all rights and benefits conferred upon Employee by the provisions of section 1542 of the California Civil Code, which provides:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY.

Employee agrees that Employee understands and Employee acknowledges the significance and the consequences of such a release, as well as the specific waiver of section 1542. This means that, should Employee discover any facts different from what Employee understood at the time Employee signed this Agreement, Employee will still be barred from making any claims against any of the Releasees.

iv. Except as expressly provided herein, Employee acknowledges and agrees that, by signing this Agreement, Employee is surrendering and giving up any right Employee has or may have, without limiting the generality of any other provision herein, to assert any claim for individual relief or damages against or involving Employer or the Releasees arising from or in any way relating to Employee's employment with Employer or the termination thereof, or to permit Employee to become and remain a member of any class seeking individual relief or damages against Employer or the Releasees arising from or in any way relating to Employee's employment with Employer or the termination thereof. Nothing herein, however, shall prevent Employee from filing a charge with or participating in any investigation or proceeding conducted by the Equal Employment Opportunity Commission or a state or local fair employment practices agency; provided, however, that Employee further agrees and understands that Employee has waived Employee's right to recover monetary damages or other relief personal to employees in any such charge, complaint, grievance or lawsuit filed by Employee or on Employee's behalf arising from, or in any way relating to, Employee's employment with Employer or the termination thereof, to the maximum extent permitted by applicable law. This release shall not apply to any claims which may not be released pursuant to applicable law and shall not apply to (1) Employee's Equity Rights and rights to enforce the Employment Agreement with respect to any claims with respect to payments and benefits under Sections 6.1(a), (d), and (f) of the Employment Agreement (and any payments and benefits under Section 6.5 of the Employment Agreement in the event that a termination occurs within twelve (12) months following a change in control), with respect to Severance and rights under Section 8.8 of the Employment Agreements, and (2) any rights in the nature of indemnification which the Employee may have with respect to claims against the Employee relating to or arising out of his employment with, or other provision of services to, the Company Entities.

v. Notwithstanding anything herein or in any other agreement with or policy of the Employer to which Employee was or is subject, nothing herein or therein shall (A) prohibit Employee from making reports of possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934, as amended, or Section 806 of the Sarbanes-Oxley Act of 2002, or of any other whistleblower protection provisions of state or federal law or regulation, or (B) require Employee to comply with any notification or prior approval requirement with respect to any reporting described in clause (A); provided, however, that Employee is not authorized to disclose communications with counsel that were made for the purpose of receiving legal advice or that contain legal advice or that are protected by the attorney work product or similar privilege. Furthermore, Employee shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made (1) in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney, in each case, solely for the purpose of reporting or investigating a suspected violation of law or (2) in a complaint or other document filed in a lawsuit or proceeding, if such filings are made under seal.

(b) *Covenant Not to Sue*. Additionally, Employee agrees not sue, commence, assert, bring or file in any court or other tribunal, in any jurisdiction, any suit, action, litigation, complaint, cross-complaint, counterclaim, third-party complaint, petition or other pleading or proceeding, or otherwise seek affirmative relief against any Releasees on account of any claim released pursuant to this Agreement. Employee represents that Employee has no charges, complaints, grievances or any other claims or requests for relief pending against Employer or the Releasees (as defined above) with the Equal Employment Opportunity Commission or any other federal, state or local administrative or other judicial tribunal and has no charges, complaints, grievances or any other claims regarding allegations of sexual harassment or sexual misconduct against the Employer.

(c) *Consideration*. The Employee acknowledges the Severance is in addition to anything of value to which the Employee already is entitled from the Employer and its affiliates and constitutes good and valuable additional consideration for this Agreement.

3. Acknowledgement of Restrictive Covenants. Employee acknowledges that Employee remains bound by his obligations pursuant to Article 8 of the Employment Agreement.

4. No Admission of Liability. Employee agrees and acknowledges that nothing contained in this Agreement, nor the fact that Employee has been or will be paid any remuneration under it, shall be construed, considered or deemed to be an admission of liability or wrongdoing by either Employer or any of the Releasees. Employer and the Releasees deny committing any wrongdoing or violating any legal duty with respect to the Employee's employment or the termination of Employee's employment from Employer. The terms of this Agreement, including all facts, circumstances, statements and documents, shall not be admissible or submitted as evidence in any litigation, in any forum, for any purpose, other than to secure enforcement of the terms and conditions of this Agreement, or as may otherwise be required by law.

5. Knowing and Voluntary Waiver; Acknowledgements.

(a) The Employee acknowledges that, by the Employee's free and voluntary act of signing below, the Employee agrees to all of the terms of this Agreement and intends to be legally bound thereby. By signing this Agreement, Employee hereby acknowledges and agrees that:

i. Employee has been afforded a reasonable and sufficient period of time to review this Agreement, for deliberation thereon and for negotiation of the terms thereof, and Employee is hereby specifically urged and advised by Employer to consult with an attorney, legal counsel or a representative of Employee's choice before signing it;

ii. Employee has carefully read and understands the terms of this Agreement, all of which have been fully explained to Employee;

iii. Employee has signed this Agreement freely and voluntarily and without duress or coercion and with full knowledge of its significance and consequences and of the rights relinquished, surrendered, released and discharged hereunder;

iv. The only consideration for signing this Agreement are the terms stated herein and no other promise, agreement or representation of any kind has been made to Employee by any person or entity whatsoever to cause Employee to sign this Agreement;

v. Employee acknowledges that Employee has been informed that Employee has the right to consider this Agreement for a period of at least 21 days prior to entering into this Agreement. Employee expressly acknowledges that Employee has taken sufficient time to consider this Agreement before signing it;

vi. Employee expressly acknowledges that, if any changes – whether material or immaterial – are or were made to this Agreement after Employee's receipt for review, such changes do not commence a new 21 day period for consideration; and

vii. Employee acknowledges that this Agreement does not waive rights or claims that may arise after the date this Agreement is signed.

(b) *Effective Date.* This Agreement will become effective, enforceable and irrevocable on the eighth day after the date on which it is executed by the Employee (the "Effective Date"), provided that the Parties acknowledge and agree that this Agreement shall be null and void if executed prior to the Termination Date. During the seven-day period prior to the Effective Date, the Employee may revoke Employee's agreement to accept the terms hereof by indicating in writing to the Employer his or her intention to revoke. If the Employee exercises Employee's right to revoke hereunder, Employee shall forfeit Employee's right to receive any Severance Payments.

6. Miscellaneous.

(a) *Non-Disclosure*. Employee acknowledges and agrees that Employee will not disclose the terms of this Agreement to anyone except for Employee's spouse, tax advisor and/or attorney, and only then after having received assurances that they too will honor this confidentiality provision.

(b) *Withholding*. The Employer may withhold from any amounts payable to the Employee all federal, state, city or other taxes that the Employer may reasonably determine are required to be withheld pursuant to any applicable law or regulation, (it being understood that the Employee shall be responsible for payment of all taxes in respect of the payments and benefits provided herein).

(c) *Severability*. Any provision of this Agreement (or portion thereof) which is deemed invalid, illegal or unenforceable in any jurisdiction shall, as to that jurisdiction be ineffective to the extent of such invalidity, illegality or unenforceability, without affecting in any way the remaining provisions thereof in such jurisdiction or rendering that or any other provisions of this Agreement invalid, illegal, or unenforceable in any other jurisdiction. If any covenant should be deemed invalid, illegal or unenforceable because its scope is considered excessive, such covenant shall be modified so that the scope of the covenant is reduced only to the minimum extent necessary to render the modified covenant valid, legal and enforceable. No waiver of any provision or violation of this Agreement by the Employer shall be implied by the Employer's forbearance or failure to take action.

(d) *Notices*. All notices given hereunder shall be in writing and shall be sent by registered or certified mail, return receipt requested, or a national overnight courier service capable of providing delivery confirmation, or by hand-delivery, or by facsimile transmission with confirmed receipt, and, if intended for the Employer, shall be addressed to it at the Employer's principal business office, Attn: General Counsel and if intended for the Employee, shall be addressed to Employee at the address on file at Employer. Each such notice shall be deemed to be given on the date received at the address of the addressee or upon refusal to accept delivery.

(e) *Entire Agreement.* This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior agreements relating thereto whether written or oral.

(f) *Execution*. This Agreement may be executed in two or more facsimiled counterparts, each of which shall be equivalent to an original, but which collectively shall constitute one Agreement.

(g) *Modification; Successors and Assigns*. This Agreement may not be modified or amended, nor may any rights under it be waived, except in a writing signed and agreed to by the Parties. This Agreement shall be binding upon, inure to the benefit of and be enforceable by the Parties and their respective successors, assigns, legal representatives, executors, administrators and heirs, provided that Employee may not assign his obligations under this Agreement. Employee acknowledges and agree that the Releasees are express third party beneficiaries of this Agreement.

7. Governing Law

(a) *Governing Law*. This Agreement shall be governed by and construed in accordance with the laws of the State of California without giving effect to the rules of conflicts of law.

(b) *Arbitration.* Any dispute, claim or controversy arising under or in connection with this Agreement or Section 13.8 of the Employment Agreement is incorporated herein in its entirety mutatis mutandis.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties hereto have executed and delivered this Agreement on the date first written above.

UNICYCIVE THERAPEUTICS INC.

By: _____
Name:
Title:

EXECUTIVE

_____
Pramod Gupta

Exhibit 10.9

AMENDMENT TO EMPLOYMENT AGREEMENT

THIS AMENDMENT TO EMPLOYMENT AGREEMENT (this "Amendment") is entered into as of April 28, 2021, by and between Unicycive Therapeutics, Inc., a Delaware corporation (the "Company"), and Pramod Gupta (the "Executive").

WHEREAS, the Company and Executive are parties to that certain Employment Agreement, dated as of March 22, 2021 (the "Employment Agreement");

WHEREAS, pursuant to the Employment Agreement, the Company and Executive agreed that Executive would be employed by the Company as its Executive Vice President, Pharmaceutical and Business Operations; and

WHEREAS, the parties desire to amend the terms of the Employment Agreement in order to clarify the parties' intent with respect to the effective date thereof.

NOW, THEREFORE, in consideration of the foregoing, the parties, intending to be legally bound, hereby agree as follows:

1. Amendment. The second paragraph on page 1 of the Employment Agreement is hereby amended in its entirety to read as follows:

"WHEREAS, the Company desires to continue to employ Executive, and Executive desires to continue to be employed by, the Company, in each case effective as of the date of an initial public offering of the Company (the 'Effective Date');"

2. Governing Law. This Amendment and the obligations of the parties hereto shall be governed by and interpreted, construed and enforced in accordance with the laws of the State of California (regardless of the laws that might otherwise govern under applicable principles or conflicts of law) as to all matters, including but not limited to matters of validity, construction, effect, performance and remedies.

3. Counterparts. This Amendment may be executed in several counterparts, each of which shall be deemed an original and all of which shall constitute one and the same instrument. Delivery may be made by the facsimile transmission of a signed counterpart.

4. Further Amendments. This Amendment cannot be changed, waived, discharged or terminated orally, but only by an instrument in writing signed by the party against whom enforcement of the change, waiver, discharge or termination is sought. The execution of any further amendment to this Amendment by all parties hereto shall establish that such execution was made in accordance with any applicable requirements for approval.

5. Entire Agreement. This Amendment constitutes the entire agreement among the parties with respect to the subject matter hereof and supersedes any prior understandings, agreements, term sheets, letters of intent or representations by or among the parties, written or oral, to the extent they related in any way to the subject matter hereof. Except as otherwise provided in this Amendment, the Employment Agreement shall remain unchanged and in full force and effect.

IN WITNESS WHEREOF, the parties hereto have executed and delivered this Amendment as of the day and year first above written.

COMPANY:

UNICYCIVE THERAPEUTICS, INC.:

By: /s/ Shalabh Gupta, M.D.
Name: Shalabh Gupta, M.D.
Title: President & CEO

EXECUTIVE:

/s/ Pramod Gupta
Pramod Gupta

[*] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

MASTER SERVICES AGREEMENT BETWEEN UNICYCIVE THERAPEUTICS, INC.AND ASCENT DEVELOPMENT SERVICES, INC.

This Master Services Agreement (this "**Agreement**") is effective as of 08 February 2021 (the "**Effective Date**") by and between Unicycive Therapeutics, Inc. a corporation organized and existing under the laws of Californa, USA and having a place of business at 5150 El Camino Real, Suite A-32, Los Altos, CA 94022 (" **Unicycive**") and Ascent Development Services, Inc., a corporation organized under the laws of Japan having a place of business at Shibuya SOLASTA 3F, 1-21-1 Dogenzaka, Shibuya-ku, Tokyo 150-0043, Japan ("**Ascent**"). Unicycive and Ascent may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, Unicycive desires to develop the investigational product Renazorb or other investigational products as agreed by the parties (the "**Compound(s)**") for clinical use in Japan and other Asian countries ("**Asian Countries**") to commercialize the Compound in Asian Countries;

WHEREAS, Unicycive desires to obtain the services of Ascent in connection with the Asian development of Unicycive's Compound(s) ("**Project**") and Ascent is willing to provide such services to Unicycive under the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the mutual promises hereinafter set forth, the Parties hereby agree as follows:

1 SERVICES AND STATEMENTS OF WORK.

1.1 **Engagement.** Unicycive hereby retains Ascent to provide certain services in connection with the Projects (the "**Services**"), and Ascent agrees to provide the Services to Unicycive under the terms and conditions of this Agreement.

1.2 **Statements of Work.** This Agreement contains general terms and conditions under which Unicycive would engage Ascent and under which Ascent would provide Services to Unicycive. Unicycive and Ascent must complete and execute a work order, project order or statement of work for each Project referencing this Agreement (each, a "**Statement of Work**") before any Services are provided. Each Statement of Work shall describe in reasonably sufficient detail, (i) the Services to be performed, (ii) the clinical study to be conducted (if applicable), (iii) the materials, reports, documentation or other deliverables to be provided to Unicycive (the "**Deliverables**"), (iv) the specifications thereto (if applicable), (v) any special terms and conditions applicable to such Services or Deliverables, (vi) an estimate of the costs and payments for such Services, (vii) the schedule for the provision of such Services and Deliverables, and (viii) the project representatives for each Party. Neither Unicycive nor Ascent is obligated to execute any Statement of Work. Once executed, each Statement of Work becomes part of this Agreement, and each such Statement of Work and this Agreement shall constitute the entire agreement for the Services provided under such Statement of Work. The terms in a Statement of Work will apply only to Services described in that Statement of Work.

1.3 **Scope of Services.** The Services to be performed by Ascent as part of a Project and pursuant to the Statement of Work for such Project may include some or all of the following:

1.3.1 Perform market research, including interviews with key opinion leaders, industry experts, and relevant organizations; collect information concerning current treatment practice and unmet medical need; and make key success factor and competitive analyses for the development of the Compound in Japan;

1.3.2 Build project management procedure and infrastructure necessary for implementation of the Services;

1.3.3 Hire and manage analysis agencies and contract research organizations ("**CROs**") to monitor and manage the progress of the Project;

1.3.4 Obtain government permission required for the conduct of clinical trials and the import of the Compound and establish the system required for safekeeping and arrangement of transportation of the Compound;

1.3.5 Prepare or translate the investigator's brochure, the informed consent form, and the clinical study protocol, and other documentation required for conduct of a clinical trial;

1.3.6 Select and retain medical professionals and experts with relevant cumulative experience and knowledge, as necessary;

1.3.7 Select medical institutions and investigators responsible for the Project and secure the number of medical institutions and trial subjects required to conduct the Project;

1.3.8 Collect and report information concerning side effects of the Compound;

1.3.9 Manage the closing process of the Project;

1.3.10 Construct a system for safekeeping, control, and maintenance of all the relevant documents throughout the required document-retention period;

1.3.11 Report on the progress and results of the Project to Unicycive;

1.3.12 Prepare and keep record of expenses incurred in performing the Services; and

1.3.13 Any other services that the Parties may specify in such Statement of Work.

1.4 **Subcontracting.** Ascent shall not subcontract the Services, in whole or in part, to any third party without the prior written consent of Unicycive. All permitted subcontracted Services shall be performed under the terms of a written agreement entered into between Ascent and a qualified subcontractor or consultant; provided, however, that Ascent shall be responsible for the performance of such subcontractors and consultants. Each such subcontract agreement shall include terms and conditions consistent with the terms and conditions of this Agreement, including without limitation terms and conditions with respect to Inventions (as defined in Section 13.2) and Confidential Information (as defined in Section 4.1) sufficient to secure and protect the rights of Unicycive consistent with the intent of this Agreement. Each such subcontract agreement shall include, to the extent permitted under applicable law, a provision that makes Unicycive a third party beneficiary of Ascent's rights under such subcontract agreement, including without limitation the right for Unicycive to enforce the confidentiality and intellectual property ownership provisions in such subcontract directly against such subcontractor.

1.5 **Changes to a Statement of Work.** During the term of this Agreement, the Parties may make changes to any Statement of Work by preparing an amendment reflecting such changes, which shall be signed by both Parties (a "**Change Order**"). The Change Order will become effective upon the execution of the Change Order by both Parties, and Ascent will be given a reasonable period of time under the circumstances within which to implement the changes, as further detailed in the Change Order. Both Parties agree to act in good faith and promptly when considering a Change Order requested by the other Party. While the Parties negotiate a Change Order, Ascent is hereby authorized to provide additional services, the performance of which shall be subject to the terms of this Agreement; provided that such additional services and any costs associated with such additional services are specifically requested and authorized in writing by Unicycive. Unicycive hereby agrees to pay for such authorized additional services at a price mutually agreed upon in writing by the Parties regardless of whether or not a Change Order is executed by the Parties.

1.6 **Instruction; Performance.** Unicycive may give instructions to Ascent in writing concerning Ascent's implementation and performance of the Services from time to time when necessary, and Ascent shall take appropriate measures in accordance with the instructions given by Unicycive, provided that, to the extent any such instructions would require a change in the applicable Statement of Work, the Parties shall execute a Change Order pursuant to Section 1.5. Ascent shall perform all Services identified in any Statement of Work (i) in compliance with (a) the terms, conditions and specifications set forth in the Statement of Work, including without limitation, the protocol for the applicable Services (as may be amended or updated from time to time by Unicycive) and (b) the terms and conditions of this Agreement, (ii) in a professional manner in accordance with accepted industry standards, and (iii) using commercially reasonable efforts to perform all Services, and deliver all Deliverables, in accordance with the timelines set forth in the Statement of Work.

2 RESPONSIBILITIES OF ASCENT

2.1 **Compliance with Government Laws and Regulations.** Ascent will perform the Services in compliance with any and all applicable national, provincial and local laws, rules and regulations, including without limitation any regulations promulgated by regulatory authorities which apply to the Services in any country or territory in which they are provided (collectively, "**Applicable Law**").

2.2 **Regulatory Filings.** Except as separately agreed to in writing between the Parties, Ascent shall be solely responsible, at the sole cost and expense of Unicycive, for preparing and filing any and all regulatory filings relating to the Project and the Services and shall be responsible for all interactions with regulatory authorities relating thereto. Ascent shall make available to Unicycive, or to the responsible regulatory authority, any and all relevant records, programs and data as may be reasonably requested by Unicycive for purposes relating to Unicycive's regulatory filings.

2.3 **Adverse Events.** In the event that under this Agreement or any Statement of Work, Ascent shall be responsible for reporting to the applicable regulatory authorities any adverse events related to the use of the Compound, Ascent shall provide Unicycive with prompt prior written notice upon becoming aware of the need to make such reports, and shall provide Unicycive with a copy of any such proposed communication with regulatory authorities for review and comment. Unicycive shall provide such comments promptly and in any event within five (5) days of receiving notice of the need for such report, and Ascent shall incorporate any reasonable comments from Unicycive in such report.

2.4 **Informed Consent.** Under this Agreement, Ascent may develop a standard form of informed consent (an "**Informed Consent**") for each Project and require each study subject to sign such Informed Consent prior to such study subject's participation in the applicable study. All such Informed Consents shall comply with the requirements of the study protocol and all Applicable Law. The approved form of Informed Consents shall include language intended to serve as appropriate authorization for the disclosure of protected health information of the applicable study subject, including without limitation all Personal Data (as defined in Section 6.1) to Ascent and Unicycive. Ascent will provide Unicycive with copies of all Informed Consents from the study sites for approval prior to being put into effect. The Informed Consents and any modifications thereto shall be subject to the approval of Unicycive and the relevant Institutional Review Board prior to any use thereof. Any transfer of responsibility for obtaining Informed Consent as required under Applicable Law will be set forth in the applicable Statement of Work.

2.5 **Study Sites.** Each study site and investigator proposed by Ascent for participation in the study must be approved by Unicycive prior to initiation of any on-site study-related activities involving that study site or investigator. Following receipt of such approval by Unicycive, Ascent will assist with negotiation and execution of a clinical trial agreement with each such investigator in the form approved by Unicycive. Unless otherwise specifically requested by Unicycive in writing or required under Applicable Law, Ascent will not contract directly as a party to any clinical trial agreements with participating study sites. The clinical trial agreements and any modifications thereto shall be subject to the written approval of Unicycive prior to any use thereof.

3 RESPONSIBILITIES OF UNICYCIVE

3.1 **Unicycive Supplied Materials.** Unicycive shall, in accordance with the applicable Statement of Work, deliver to Ascent, at Unicycive's cost and expense, any and all materials, including but not limited to the Compound, identified in the Statement of Work as Unicycive's responsibility to deliver to Ascent or otherwise agreed to between the Parties (collectively, the "**Unicycive Supplied Materials**"). Unicycive shall at all times retain title to any and all Unicycive Supplied Materials. Ascent shall provide storage of the Unicycive Supplied Materials in accordance with the applicable specifications for such Unicycive Supplied Materials as supplied by Unicycive to Ascent. Ascent shall only use the Unicycive Supplied Materials for the purpose of conducting the Projects and for no other purpose. Ascent shall not allow any Unicycive Supplied Materials to be transferred to any third parties not authorized by Unicycive. If any quantity of the Compound or any Unicycive Supplied Materials are lost, damaged, or destroyed (unless authorized by Unicycive in writing) while in Ascent's control due to the negligent or intentional act or omission of Ascent or its employees or agents, Ascent will promptly provide Unicycive with appropriate documentation as to the occurrence, and, in Unicycive's sole discretion, Ascent shall be liable to Unicycive for the replacement cost of such Compound or such Unicycive Supplied Materials. Ascent shall maintain complete and accurate records accounting for and documenting the use of all Unicycive Supplied Materials.

3.2 **Fees and Expenses.** Unicycive shall pay Ascent for the Services performed under this Agreement and any Statement of Work in accordance with the rates for such Services set forth in such Statement of Work, including any bank transfer and currency exchange fees associated with each payment. Ascent shall invoice Unicycive according to the terms in the applicable Statement of Work.

3.3 **Side Effects.** Ascent shall notify Unicycive immediately in writing upon becoming aware of any side effects arising from the use of the Compound in relation to the Project. Unicycive shall provide Ascent with information on side effects with respect to the Compound within a reasonable period of time after Unicycive becomes aware of any such side effects.

4 CONFIDENTIALITY

4.1 **Confidential Information.** "Confidential Information" means any and all confidential or proprietary information and materials that will be or have been disclosed or otherwise provided by either Party (the "**Discloser**") to the other Party (the "**Recipient**") in writing, physically, orally or visually in connection with the Services, and that: (a) is identified as confidential or proprietary at the time of disclosure; or (b) by its nature should reasonably be understood by the Recipient to be confidential or proprietary. Confidential information shall include, without limitation, any and all information concerning Discloser's know-how, data, specifications, documents, techniques, processes, protocols, formulae, chemical structures and identity, product samples, computer programs, software, apparatus, reports, trade secrets, business plans, referral sources, billing information, fee structures, identity and compensation to employees, contracts and leases, client lists, business models, technology, data, plans, specifications, study management tools, or other information, and any and all of such information that the Discloser is under an obligation to a third party to maintain as confidential.

4.2 **Protection of Confidential Information.** The Parties acknowledge that in the course of the work hereunder, it will be necessary for each Party to disclose Confidential Information to the other Party. Each Party, as a Recipient, agrees not to transfer or otherwise disclose any Confidential Information to any third party, and not to use the Confidential Information except solely to perform its obligations under this Agreement. Each Party, as a Recipient, (i) may disclose Confidential Information solely to those of its affiliates, employees, representatives, agents, independent consultants and advisors (collectively, "**Representatives**") on a need-to-know basis who are bound by written obligations of non-disclosure and non-use no less protective than those contained herein, and (ii) shall take the same precautions to protect against unauthorized disclosure or use of such Confidential Information that such Party takes to protect its own confidential information, but in no event less than a reasonable standard of care.

4.3 **Exception to Confidentiality Obligation.** Notwithstanding the foregoing, the confidentiality and non-use obligations set forth in this Article 4 shall not apply to:

4.3.1 Information which the Recipient can prove to have already been known to or possessed by it prior to the disclosure by Discloser, provided that the source of such information was not known by the Recipient or its Representatives to be bound by a confidentiality obligation to the Discloser;

4.3.2 Information which has already been known to the public prior to its disclosure to the Recipient by or on behalf of the Discloser;

4.3.3 Information which becomes known to the public after the disclosure without any fault of the Recipient;

4.3.4 Information which is lawfully received by the Recipient from a third party having legitimate authority to disclose such information and not bound by a confidentiality obligation to the Discloser; and

4.3.5 Information which is independently developed by Recipient without access to or use of the Confidential Information of the other Party.

4.4 **Required Disclosure of Confidential Information.** The Recipient may disclose Confidential Information of the Discloser to a court or other government body of competent jurisdiction when required to do so pursuant to an order of such body or if otherwise required to do so pursuant to Applicable Law (including without limitation in connection with filings with the United States Food and Drug Administration, the United States Securities and Exchange Commission, or any other applicable governmental agency) or the rules of any securities exchange, provided it uses reasonable efforts (i) to give prompt prior notice to the Discloser to contest such order, and (ii) to limit disclosure to that which is required pursuant to Applicable Law.

4.5 **Effect of Termination.** Upon termination of this Agreement, all Confidential Information (and all copies thereof) furnished to the Recipient or its Representatives by or on behalf of the Discloser pursuant hereto, shall be, at the Discloser's option, returned to the Discloser or destroyed and no copy thereof shall be retained, except (i) that a single copy of all such Confidential Information may be retained in confidence by the Recipient's internal or outside legal counsel solely for the purposes of determining its obligations hereunder, and (ii) the Recipient may retain one or more copies of Confidential Information if the Recipient is required to retain one or more copies of any such Confidential Information to comply with all Applicable Law. The Recipient and its Representatives will continue to be bound by its obligations of non-use and non- disclosure of Confidential Information of the Discloser under this Agreement for seven (7) years after termination of this Agreement; provided, however, that the obligations of the Recipient and its Representatives with respect to trade secrets of the Discloser shall continue perpetually after termination of this Agreement.

4.6 **Equitable Relief.** The Parties acknowledge that remedies at law may be inadequate to protect the Discloser against any actual or threatened breach by the Recipient or its Representatives of the confidentiality provisions of this Agreement, and, without prejudice to any other rights and remedies otherwise available to the Discloser, the Discloser may seek injunctive relief in the Discloser's favor to bar the use or disclosure of Confidential Information without proof of actual damages or requirement to post bond.

5 REPRESENTATIONS AND WARRANTIES

5.1 **Representations of Each Party.** Each Party represents, warrants and covenants to the other Party that:

5.1.1 It is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder; and

5.1.2 The terms of this Agreement are not inconsistent with, or do not constitute a violation of, any contractual or other legal obligation to which such Party is subject.

5.2 **Representations of Unicycive.** Unicycive represents, warrants and covenants to Ascent that:

5.2.1 Unicycive shall perform its activities under this Agreement in compliance with Applicable Law; and

5.2.2 All Compound supplied by Unicycive to Ascent for use in studies as part of a Project shall be manufactured in compliance with current Good Manufacturing Practices as required by applicable regulatory authorities.

5.3 **Representations of Ascent.** Ascent represents, warrants and covenants to Unicycive that:

5.3.1 Ascent shall perform the Services in a professional and workmanlike manner in accordance with Applicable Laws and regulations in the countries or territories in which Services are provided as well as any clinical study protocols or standard operating procedures described in the applicable Statement of Work;

5.3.2 The Deliverables shall comply with any applicable specifications set forth in the applicable Statement of Work;

5.3.3 The Deliverables shall be free and clear of all liens, claims, encumbrances or demands of third parties, including any claims by any such third party of any right, title or interest in or to the Deliverables;

5.3.4 Ascent is not currently employing/contracting any individual/organization who has been (i) debarred pursuant to 21 U.S.C. § 335a (a) or (b); 306(A) or 306(B) of the Generic Drug Enforcement Act of 1992, (ii) disqualified as a testing facility under C.F.R. Part 58, Subpart K, or (iii) disqualified or restricted under 21 C.F.R. 312.70 or, in each of cases (i)-(iii), under any similar laws or regulations in other countries in which Services are provided, from providing services in any capacity to a person that has an approved or pending drug product application under any Applicable Law (a "**Debarred Individual**") or an employer, employee or partner of a Debarred Individual;

5.3.5 Ascent has never been and is not currently a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. § 335a (a) or (b) or barred by the applicable regulatory authorities in any other country or territory pursuant to similar laws or regulations (a "**Debarred Entity**") or an employee, partner, shareholder, member, subsidiary or affiliate of a Debarred Entity;

5.3.6 Ascent will not use in any capacity under this Agreement the services of any individual, corporation, partnership, or association that has been (i) debarred under 21 U.S.C. § 335a (as shown in the most recently published FDA debarment list) or (ii) disqualified as a clinical investigator under the provision of 21 C.F.R. § 312.70 (as shown in the most recently published FDA debarment list) or, in each of cases (i) and (ii), any similar laws or regulations in the countries or territories in which Services are provided; and

5.3.7 If Ascent becomes aware of the debarment or disqualification of any such individual, corporation, partnership, or association providing Services under this Agreement, Ascent shall immediately notify Unicycive.

6 PROTECTION OF PERSONAL DATA

6.1 **Personal Data.** With respect to the treatment of any personally identifiable information ("**Personal Data**") that may come to the knowledge or possession of either Party in connection with any Project, any Statement of Work, the Services or otherwise under this Agreement, each Party represents and warrants to the other Party that it shall comply with the personal information protection laws, regulations and guidelines which may be applicable to the use or security of Personal Data (collectively, the "**Applicable Data Privacy Laws**").

6.2 **Security.** Each Party shall take appropriate security measures to prevent unauthorized access to, or unauthorized disclosure, use, loss or theft of such Personal Data from occurring in order to ensure protection of privacy of individuals, as required under Applicable Laws.

6.3 **Security Breaches.** If Ascent becomes aware of any breach of an Applicable Data Privacy Law relating to the Services, then it shall promptly notify Unicycive and, if requested, assist Unicycive in meeting any obligations under Applicable Data Privacy Law to notify regulatory authorities or other required parties at no additional cost to Unicycive.

7 MONITORING

7.1 **Records.** Ascent shall maintain all materials, information, source documents, correspondence, and data obtained or generated by Ascent or its affiliates, employees, agents, consultants, or contractors in the course of providing the Services hereunder, including without limitation all electronic media, computerized records and files (collectively "**Records**") in accordance with this Agreement, the Statement(s) of Work and Applicable Law in a safe and secure manner protected from fire, theft, disclosure, and destruction.

7.2 **Monitoring.** Unicycive may take reasonable measures, including audit, review or inspection of the Records or any of Ascent's facilities, personnel, documentation, procedures, equipment, records and activities used in performing the Services ("**Performance Monitoring**") from time to time as necessary to verify that all the Services are performed properly and appropriately by Ascent in accordance with the terms of this Agreement, the Statement(s) of Work and Applicable Law. Ascent shall cooperate with Unicycive in the Performance Monitoring.

7.3 **Reporting.** Upon request of Unicycive from time to time, Ascent shall report the progress of the Services, any results obtained and any other relevant information.

8 DELIVERABLES

8.1 **Submission of Deliverables.** Ascent shall submit to Unicycive all Deliverables in the form and manner and in accordance with the schedule to be mutually agreed upon in the applicable Statement of Work.

8.2 **Inspection of Deliverables.** Upon receipt of the Deliverables, Unicycive shall have the right to inspect such Deliverables. If Unicycive finds that such Deliverables fail to comply with any applicable specification set forth in the applicable Statement of Work, or if Ascent otherwise breaches its obligations in the performance of the Services that renders the Deliverables partially or wholly invalid or unusable, Unicycive may reject such Deliverables by notifying Ascent promptly of such rejection.

8.3 **Correction of Deliverables.** If Unicycive rejects any Deliverables under Section 8.2, Ascent shall use its best efforts to cure the breach that constitutes the basis of such rejection without cost to Unicycive. If such breach cannot be reasonably cured, Ascent shall (i) return to Unicycive any and all payments made by Unicycive to Ascent in regards to the defective Deliverable or applicable Services, and (ii) reimburse Unicycive for the actual replacement cost of any Unicycive Supplied Materials consumed during Ascent's performance of such Services.

8.4 **Ownership of Deliverables.** Subject to the provisions of Article 4 and Section 13.1, the Parties hereby acknowledge and agree that Unicycive shall own all right, title and interest in and to the Deliverables and that the Deliverables shall be deemed the Confidential Information of Unicycive.

9 CUSTODY OF MATERIALS

9.1 **Custody of Materials.** Unless and until delivered by Ascent to Unicycive, Ascent shall keep in its custody any unused Unicycive Supplied Materials, the Deliverables and the Records (collectively, the "**Materials**") in an appropriate manner and prevent loss, damage, theft and unauthorized use or disclosure of Materials from occurring. Ascent shall not use any part of the Materials for any purpose other than to provide the Services under this Agreement and the Statement(s) of Work.

9.2 **Return or Delivery of Materials.** Upon request of Unicycive, Ascent shall return or deliver to Unicycive all requested Materials, including copies thereof, promptly. Upon any expiration or termination of this Agreement, Ascent shall promptly return to Unicycive or a third party designated in writing by Unicycive, at Unicycive's reasonable cost and expense, any and all Materials under Ascent's control, including copies thereof.

9.3 **Retention by Ascent.** If Unicycive requests Ascent to keep any Materials or any part thereof after the completion of Services, Ascent shall keep them in such manner and for such time as shall be agreed through consultation between the Parties.

10 INVESTIGATIONS BY REGULATORY AUTHORITIES

10.1 **Investigations by Regulatory Authorities.** Ascent shall promptly notify Unicycive of any regulatory inspection relating to the Services by a duly authorized representative ("**Inspector**") of any government agency or other regulatory entity. Ascent shall provide Unicycive with the following data as soon as practicable: (i) the purpose of the inspection, (ii) the name and credential number of the Inspector, and (iii) a copy of all materials, correspondence, statements, forms, and records received or generated pursuant to such inspection or audit. Unless otherwise required by Applicable Law, Ascent shall not permit any inspection or audit relating to the Services or Unicycive's Confidential Information without Unicycive's prior written approval. In the event that Ascent does not receive prior notice of such regulatory inspection or audit, Ascent shall notify Unicycive as soon as practicable after such regulatory inspection or audit, and will provide in writing to Unicycive copies of all materials, correspondence, statements, forms, and records received or generated pursuant to such inspection or audit. Unicycive shall have the primary responsibility for preparing any responses relating to the Services that may be required by the government agency or regulatory entity; provided, however, that Ascent shall have the primary responsibility for preparing any responses relating to the method of performing the Services and Ascent's operations and procedures. Ascent shall provide any proposed correspondence with government agencies or other regulatory entities related to the Services, including without limitation any such responses, to Unicycive for Unicycive's review and approval before submission. Ascent shall take all reasonable actions requested by Unicycive to cure any deficiencies noted during any such inspection or audit. Unicycive shall be responsible for the costs and expenses incurred in connection with preparing any responses to such investigation or audit.

11 INDEMNIFICATION

11.1 **Unicycive Obligations.** Unicycive shall indemnify and hold harmless Ascent, its affiliates, officers, directors, representatives and employees from and against any claims, demands, suits, actions, losses, damages, expenses and other liabilities (including without limitation court costs, legal fees, awards or settlements) (each, a "**Liability**") arising from (i) Unicycive's negligence or willful misconduct, (ii) Unicycive's breach of this Agreement or any Statement of Work, or (iii) personal injury or death arising as a result of use or administration of any Unicycive study drug or device, including the Compound, to any study subject in accordance with the terms of the applicable Statement of Work, except to the extent that any such Liabilities are subject to Ascent's indemnification obligations under Section 11.2.

11.2 **Ascent Obligations.** Ascent shall indemnify and hold harmless Unicycive, its affiliates, officers, directors, representatives and employees from and against any Liability arising from (i) Ascent's negligence or willful misconduct, or (ii) Ascent's breach of this Agreement or any Statement of Work, except to the extent that any such Liabilities are subject to Unicycive's indemnification obligations under Section 11.1.

11.3 **Notification.** Each Party seeking indemnification under this Article 11 shall, as a condition thereto, notify the indemnifying Party promptly (such period not to exceed ten (10) days) after the receipt of notice of the Liability; provided, however, that the indemnifying Party shall not be released from its obligations under this Article 11 if any failure to promptly notify the indemnifying Party does not materially prejudice the defense of such Liability. The indemnifying Party shall have the right to select defense counsel and to direct the defense or, with the consent of the indemnified Party (which consent shall not be unreasonably withheld) settlement of, any Liability. In the event that representation of an indemnified Party and the indemnifying Party by the same counsel would be a conflict of interest for such counsel, the indemnified Party may select its own independent counsel without relieving the indemnifying Party of its obligations under this Article 11. Under no circumstances shall an indemnified Party settle or otherwise compromise any Liability without the indemnifying Party's prior written consent.

12 INSURANCE

12.1 **Insurance.** Ascent shall maintain in force during the term of this Agreement, at its own cost and expense, insurance in quantities and types as is customary in the industry for the type of Services to render under the Agreement. Upon request by Unicycive, Ascent shall provide to Unicycive evidence of such insurance.

13 INTELLECTUAL PROPERTY RIGHTS

13.1 **Existing Technologies.** Each Party owns and shall retain all right, title and interest in, to and under any and all intellectual property controlled by such Party prior to the Effective Date, and, except as expressly set forth in this Agreement, no right or license to such prior intellectual property is granted by either Party to the other Party. Notwithstanding the foregoing, in the event that any intellectual property owned or controlled by Ascent prior to the Effective Date, or developed and owned or controlled by Ascent after the Effective Date, without reference to or reliance upon the Compound, any Unicycive Confidential Information or any Unicycive Supplied Materials (the "**Ascent IP**") is incorporated into the Deliverables, Ascent hereby grants Unicycive a non-exclusive, perpetual, royalty-free, fully paid, transferable, sublicenseable license under the Ascent IP to the extent required for Unicycive to use the Deliverables.

13.2 **Inventions.** Unicycive shall own all right, title and interest in and to the Compound, the Unicycive Supplied Materials and any and all materials, documents, information, protocols, and procedures generated, conceived or developed by Ascent in the course of or as a result of the Services performed hereunder, including without limitation the Deliverables, excluding any Ascent IP. Unicycive shall own all rights, title and interest in any ideas, inventions, discoveries, techniques, methods, processes, trade secrets or other know-how, whether patentable or not, that (i) relate to the Unicycive Supplied Materials (including without limitation the Compound), (ii) arise from the materials, documents, information, protocols, or procedures above described, or which are generated, conceived or developed in the course of or as a result of the Services performed under this Agreement and any Statement of Work, or (iii) arise as a result of Unicycive's disclosure of Confidential Information to Ascent, and for each of cases (i)- (iii), any and all intellectual property therein (collectively, the "**Inventions**"). Ascent hereby assigns to Unicycive all of Ascent's right, title and interest in and to the Inventions and agrees to take all reasonable actions necessary to give effect to such assignments, and Unicycive agrees to reimburse Ascent for reasonable expenses incurred in relation to such activities.

13.3 **Assignment by Employees.** Ascent hereby represents that all employees, consultants, and any other permitted persons acting on Ascent's behalf during its performance of the Services shall be obligated to assign to Unicycive, or obligated to assign to Ascent , and Ascent assigns to Unicycive pursuant to Section 13.2, all rights to any and all Inventions conceived or developed by such employees or other persons and to take all reasonable actions necessary to give effect to such assignments. Unicycive agrees to reimburse Ascent for reasonable expenses incurred in relation to such activities.

14 TERM AND TERMINATION

14.1 **Term.** This Agreement shall become effective as of the Effective Date and shall continue in full force and effect until terminated by either Party in accordance with this Article 14, provided that in the event that there are Services being provided under any Statement of Work at the date of termination of this Agreement, then subject to Section 14.6, this Agreement and all such Statements of Work shall remain in force upon their terms until the completion of all Services under such Statement of Work, unless Unicycive requests in writing that Ascent also terminates the provision of Services under such Statement of Work earlier. Subject to the foregoing sentence, each Statement of Work shall be effective upon the date specified therein and shall terminate upon the later of (i) the completion of the Services to be provided thereunder; or (ii) Ascent's receipt of all fees due under such Statement of Work, unless earlier terminated pursuant to this Article 14.

14.2 **Termination for Convenience.** Unicycive may, upon thirty (30) days' prior written notice to Ascent, terminate this Agreement or any Statement of Work at any time and for any reason. Ascent may terminate this Agreement upon sixty (60) days prior written notice to Unicycive at any time, provided that such termination will not be effective with respect to any Statements of Work under which Ascent is providing Services at the date of such termination, until the completion of all Services under such Statements of Work.

14.3 **Termination for Insolvency.** Either Party may terminate this Agreement and all Statements of Work immediately upon provision of written notice if the other Party files for insolvency or bankruptcy or equivalent proceeding in any jurisdiction, and such filing is not dismissed within sixty (60) days after such filing.

14.4 **Termination for Breach.** In the event either Party breaches any material term of this Agreement or any Statement of Work and if such breach has not been cured within thirty (30) days after the breaching Party's receipt of written notice of such breach from the non-breaching Party, the non-breaching Party may terminate this Agreement or the applicable Statement of Work immediately.

14.5 **Effects of Termination.** Termination of this Agreement pursuant to this Article 14 shall not affect other remedy, statutory or contractual, otherwise available to the terminating Party, including the right to claim damages against the other Party.

14.6 **Payments on Termination.** If this Agreement is terminated under any circumstances, Unicycive shall pay all reasonable costs, if any, actually incurred for Services performed prior to the date of termination; provided, however that Ascent shall not continue performing Services after receipt of notice of termination except to the extent specifically authorized by Unicycive. The total of such payments, including without limitation any non-cancelable costs incurred by Ascent in performing the Services, shall not exceed the aggregate maximum budgets established in all applicable Statements of Work. If an individual Statement of Work is terminated under any circumstances, Unicycive shall pay all reasonable costs, if any, actually incurred for Services performed prior to the date of termination; provided, however that Ascent shall not continue performing Services after receipt of notice of termination except to the extent specifically authorized by Unicycive. The total of such payments, including without limitation any non-cancelable costs incurred by Ascent in performing the Services, shall not exceed the maximum budget established in such Statement of Work. Ascent shall use all reasonable efforts to mitigate termination and wind down costs to Unicycive. If it is necessary for Ascent to incur additional costs not specified in a Statement of Work in winding down any Services following the date of notice of termination of this Agreement or an individual Statement of Work, Ascent shall notify Unicycive in writing of such costs and their amount, and seek Unicycive's consent to such expenditure, such consent not to be unreasonably withheld or delayed; provided that any wind-down costs incurred as a result of termination of this Agreement or any Statement of Work for Ascent's material breach under Section 14.4 shall be the responsibility of Ascent. Unicycive shall have no liability for wind-down costs incurred without its consent. In the event of any dispute of payments hereunder, Unicycive shall pay the undisputed amounts and the parties shall work together to resolve any disputed amounts as promptly as possible. Any prepayments or overpayments by Unicycive, after subtracting any amounts owed by Unicycive to Ascent pursuant to this Section 14.6, shall be refunded in full to Unicycive, within thirty (30) days following the effective date of termination of this Agreement.

14.7 **Survival.** Articles 4 (Confidentiality) (for the period of time specified in Section 4.5), 6 (Protection of Personal Data), 10 (Investigations by Regulatory Authorities), 11 (Indemnification), 12 (Insurance) (for the period of time specified therein), 13 (Intellectual Property Rights), 15 (Disclaimer; Limitation of Liability) and 16 (Miscellaneous), and Sections 8.3 (Correction of Deliverables), 8.4 (Ownership of Deliverables), 9.1 (Custody of Materials), 9.2 (Return or Delivery of Materials), 9.3 (Retention by Ascent) (for any period of time beyond expiration or termination agreed by the Parties), 14.5 (Effects of Termination), 14.6 (Payments on Termination), and this 14.7 (Survival) of this Agreement shall survive the expiration or termination of this Agreement.

15 DISCLAIMER; LIMITATION OF LIABILITY

15.1 **Disclaimer.** EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY, AND BOTH PARTIES HEREBY DISCLAIM ALL, REPRESENTATIONS AND WARRANTIES, WHETHER EXPRESS, IMPLIED OR STATUTORY, WRITTEN OR ORAL, INCLUDING WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE AND NONINFRINGEMENT.

15.2 **Limitation of Liability.** EXCEPT FOR BREACH OF A PARTY'S CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 4 OR ITS INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 11, UNDER NO CIRCUMSTANCES WHATSOEVER WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION LOST PROFITS OR LOSSES RESULTING FROM BUSINESS INTERRUPTION, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF SUCH DAMAGES. EXCEPT FOR ITS INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 11, IN NO EVENT SHALL EITHER PARTY'S LIABILITY FOR ANY AND ALL CLAIMS, LOSSES OR DAMAGES ARISING OUT OF OR RELATING TO, IN WHOLE OR IN PART, THIS AGREEMENT, ANY STATEMENT OF WORK, OR ANY SERVICES PROVIDED HEREUNDER OR THEREUNDER EXCEED THE TOTAL AMOUNT OF ALL FEES PAID BY Unicycive TO ASCENT UNDER THE STATEMENT OF WORK PURSUANT TO WHICH SUCH LIABILITY AROSE.

16 MISCELLANEOUS

16.1 **Governing Law and Jurisdiction.** This Agreement shall be governed by the laws of Japan. The Parties hereby agree that Japan, shall have exclusive jurisdiction as a court of first instance over any dispute that may arise in connection with this Agreement which cannot be settled amicably by the Parties.

16.2 **Entire Agreement.** This Agreement, together with any Exhibits and all executed Statements of Work, each of which are incorporated into this Agreement, sets forth the entire understanding of the Parties with respect to the subject matter hereof and supersedes all prior and contemporaneous agreements and understandings between them concerning such subject matter. If there is any conflict, discrepancy or inconsistency between the terms of this Agreement and any Statement of Work, the terms of this Agreement will control unless otherwise expressly provided in the applicable Statement of Work. Any amendment to or additions to this Agreement or any Statement(s) of Work shall not be binding unless rendered in writing and signed or sealed by the duly authorized representatives of each of the Parties.

16.3 **Assignment; No Third Party Beneficiaries.** Neither Party shall assign this Agreement, any Statement or Work, or any rights or obligations hereunder or thereunder without the prior written approval of the other Party; provided, however, without such consent, either Party may assign this Agreement or a Statement of Work to an affiliate or a successor in interest by reason of merger, acquisition or sale of substantially all of the business to which this Agreement relates. No person or entity not a party to this Agreement (other than permitted successors and assigns) shall have any rights under or by virtue of this Agreement.

16.4 **Amendment & Waiver.** No change, modification, or addition or amendment to this Agreement, or waiver of any term or condition of this Agreement, is valid or enforceable unless in writing and signed and dated by the authorized officers of both Parties. No change, modification or addition or amendment to any Statement of Work, or waiver of any term or condition of any Statement of Work, is valid or enforceable unless included in a Change Order executed by both parties pursuant to Section 1.5. Any waiver of any breach of any term or condition shall not be deemed to be a waiver of any preceding or succeeding breach of the same or any other term or condition. The failure of any Party to insist upon strict performance of any term or condition hereunder shall not constitute a waiver of, or otherwise impair, such Party's right to demand strict compliance therewith in the future.

16.5 **Notices.** All notices and other communications required or permitted under this Agreement shall be in writing, electronic mail or by confirmed fax, and shall be deemed to have been duly given (i) upon personal delivery, (ii) upon deposit with a recognized courier with next-day delivery instructions, (iii) one (1) business day after sending, if sent by electronic mail and no delivery failure notification has been received, or (iv) upon confirmation of transmission, if sent by confirmed fax, to the address or fax number set forth below or such other address or fax number as either Party may specify by notice sent in accordance with this Section 16.5:

Unicycive: Unicycive Therapeutics, Inc.
5150 El Camino Real, Suite A-32,
Los Altos, CA 94022
Email: pramod.gupta@unicycive.com

Ascent: Ascent Development Services, Inc.
Shibuya SOLASTA 3F, 1-21-1 Dogenzaka, Shibuya-ku,
Tokyo 150-0043, Japan
Attn: John Winebarger
Email: john.winebarger@ascent-dev.com

16.6 **Severability.** If one or more of the provisions of this Agreement is held to be invalid or unenforceable, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

16.7 **Force Majeure.** If the performance of this Agreement or any Statement of Work by either Party is prevented, restricted, interfered with or delayed (either totally or in part) by reason of any cause beyond the reasonable control of the Party whose performance is so affected, such as acts of God, explosion, disease, extreme weather, earthquake, war, insurrection, civil strike, riots, or power failure, such affected Party shall, upon giving written notice to the other Party, be excused from such performance during the pendency, and to the extent of such prevention, restriction, interference or delay; provided, that the affected Party shall use commercially reasonable efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed.

16.8 **Independent Contractors.** The relationship established between the Parties by this Agreement is that of independent contractors, and nothing contained herein shall be construed to (i) give either Party the power to direct and/or control the day-to-day activities of the other, (ii) constitute the Parties as partners, joint venturers, co-owners or otherwise as participants in a joint or common undertaking, or (iii) allow a Party to create or assume any obligation on behalf of the other Party, or to bind the other Party in regard of to any contract, agreement or undertaking with a third party, for any purpose whatsoever, except as contemplated by this Agreement or any Statement of Work.

16.9 **Counterparts; Electronic Delivery.** This Agreement may be executed simultaneously in two counterparts, either one of which need not contain the signature of more than one Party but both such counterparts taken together shall constitute one and the same agreement. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.

Unicycive Therapeutics, Inc.

Signature: /s/ *Shalabh Gupta*
Name: Shalabh Gupta, MD, MPA
Title: President & CEO
Date: Feb 18, 2021

Ascent Development Services, Inc.

Signature: /s/ *John Winebarger*
Name: John Winebarger
Title: CEO
Date: 2021年2月19日

STATEMENT OF WORK NO. 1

This Statement of Work No. 1, together with the attached Appendix A ("Budget and Payment Terms") and Appendix B ("Description and Tentative Timeline for Services") (collectively, this "**Statement of Work**"), is agreed as of 08 February 2021 (the "**Effective Date**") pursuant to the Master Services Agreement ("**MSA**") dated 08 February 2021, between Unicycive Therapeutics, Inc. ("**Unicycive**") and Ascent Development Services, Inc. ("**Ascent**"). All of the terms, covenants, and conditions set forth in the MSA are incorporated herein by reference as if the same had been set forth herein in full. Unless otherwise defined in this Statement of Work, all capitalized terms shall have their respective meanings ascribed to them in the MSA.

1. **Project Name:** Strategic Development and PMDA Informal and Formal Consultations

2. **Term:** The term of this Statement of Work shall begin on the Effective Date and end on or about 31 December 2021.

3. **Product:** Renazorb

4. **Unicycive Manager:** Pramod Gupta, Head of Development

5. Description of and Tentative Timeline for Services: See Appendix B.

6. **Maximum amount Unicycive is required to pay:** *(including pass- through costs).

7. **All Invoices must contain:** Statement of Work Number, Product Name, Protocol Number(s) (if applicable), Unicycive contact name, Date(s) of Service, Unicycive Finance Code(s)

8. **Invoices should be sent to:** unicycive@bill.com

Unicycive Therapeutics, Inc.
5150 El Camino Real, Suite A-32,
Los Altos, CA 94022

IN WITNESS WHEREOF, the Parties hereto have executed this Statement of Work as of the Effective Date.

Unicycive Therapeutics, Inc.

By: /s/ Shalabh Gupta
Name: Shalabh Gupta, MD, MPA
Title: President & CEO
Date: Feb 18, 2021

Ascent Development Services, Inc.

By: /s/ *John Winebarger*
Name: John Winebarger
Title: CEO
Date: 2021年2月19日

APPENDIX A

BUDGET AND PAYMENT TERMS

1) This entire project costs for providing the Services described in Appendix B are as follows:

Total Direct Fees	Travel & Other Pass-Thru Costs	TOTAL COSTS
¥ *	¥ *	¥ *

2) Unicycive shall remit payments to Ascent according to the following schedule:

Upon execution of this Statement of Work, Unicycive shall make an Upfront Payment equal to 50% of the estimated total direct costs (¥*) and thereafter Ascent shall invoice Unicycive on a monthly time and materials basis for the time actually spent engaged in providing the Services. Ascent shall not invoice Unicycive for direct fees in excess of ¥*. The amount of each invoice shall reflect the Upfront Payment as a credit.

3) Ascent shall additionally invoice Unicycive on a monthly basis for various pass-through costs incurred and provide appropriate documentation of the expenses. Ascent shall obtain written approval from Unicycive prior to incurring pass-through costs in excess of the projected total of ¥*.

4) Unicycive shall make payment to Ascent immediately upon receipt of an undisputed invoice for the Upfront Payment, and within 30 days of receipt of any undisputed invoice for the remaining monthly payments consistent with the terms of the Agreement**.**

APPENDIX B

DESCRIPTION AND TENTATIVE TIMELINE FOR SERVICES

Ascent shall provide Services related to Informal and Formal PMDA Consultations for Renazorb (the "**Project**").

1. PROJECT

1.1. Scope of Work

The scope of activities to be conducted by Ascent related to the Project shall include but not limited to the following:

Informal PMDA Meeting

- Informal PMDA Meeting Application Process
  - US Non-clinical Data Package Review and Proposal of Japanese Non- clinical Data Package
  - Preparation of Executive Summary for Renazorb and development strategy and creation of development/ scientific slide deck to reflect Japan strategy
  - Discussion of Executive Summary and slide deck via TC with Unicycive to gain detailed strategic consensus
  - Discussion of Renazorb & strategy with 1 KOL & reporting to Unicycive
  - Application to PMDA (including Executive Summary) and maintenance of administrative communication with PMDA through meeting
- Informal PMDA Meeting Prep & Execution
  - Finalization of strategy and slide deck through TCs with Unicycive
  - Preparation for and conduct of PMDA meeting & conduct wrap up
  - Planning for and conduct of face-to-face meeting with KOL
  - Creation of meeting minutes for PMDA and KOL meetings

Formal PMDA Meeting

- Formal PMDA Meeting Application Process
  - Provision of guidance for Unicycive to prepare English language scientific explanation of Renazorb and its Japan development strategy based on FDA Pre-IND documentation which will be used as a guide to create the Japanese language Briefing Document (The Japanese Briefing Document will not be a literal translation)
  - Creation of Japanese Language Briefing Document and provision of AI English back-translation
- Formal PMDA Meeting Preparation & Execution
  - Submission of Briefing Document to PMDA and management of 6-week Q&A process with PMDA
  - Conduct of preparatory meetings with Unicycive with KOL, execution of PMDA and wrap up meetings, and finalization of meeting minutes with PMDA

1.2. Budget

CLINICAL STRATEGY / INFORMAL PMDA MEETING COSTS	
Informal PMDA Meeting Application Process	**Costs**
US Non-clinical Data Package Review and Proposal of Japanese Non-clincal Data Package	*
Prepare Executive Summary for Renazorb & development strategy and create development/ scientific slide deck (English) to reflect Japan strategy	*
Discuss Executive Summary and slide deck via TC with Unicycive to gain detailed strategic consensus	*
Ascent discusses Renazorb & strategy with 1 KOL & reports to Unicycive	*
Create Executive Summary in Japanese for PMDA	*
Apply to PMDA (including Executive Summary) and maintain administrative communication with PMDA through meeting	*
Informal PMDA Meeting Prep & Executiveution	
Finalize strategy and slide deck in English through TCs with Unicycive	*
Translate final slide deck into Japanese	*
Prepare for and conduct PMDA meeting & conduct wrap up	*
Plan for and conduct F2F meeting with KOL	*
Produce meeting minutes for PMDA and KOL meetings	*
Subtotal (Direct) JPY	*
Passthrough Costs	
Meeting Rooms & Miscellaneous	*
Simultaneous Interpreters	*
Subtotal Passthrough Costs JPY	*
TOTAL COST JPY (KOL/ Informal/ Strategy)	*
CLINICAL FORMAL PMDA MEETING COSTS	
Formal PMDA Meeting Application Process	
Ascent provides guidance for Unicycive to prepare English language scientific explanation of Renazorb and its Japan development strategy based on FDA Pre-IND documentation- which will be used as a guide to create the Japanese language Briefing Document (the Japanese Briefing Document will not be a literal translation)	*
Create Japanese Language Briefing Document and provide AI English back-translation	*
Formal PMDA Meeting Prep & Executiveution	
Submit Japanese Briefing Document to PMDA and manage 6-week Q&A process with PMDA (typically 3 review cycles with numerous telephone and email communications, includes Slide Deck preparation for Formal Meeting)	*
Conduct preparatory meetings with Unicycive with KOL, Executiveute PMDA and wrap up meetings, and finalize meeting minutes with PMDA	*
Subtotal (Direct) JPY	*
Passthrough Costs	
Meeting Rooms & Miscellaneous	*
Simultaneous Interpreters	*
PMDA User Fees	*
Subtotal Passthrough Costs JPY	*
TOTAL COST JPY (Formal PMDA Consultation)	*
COMBINED INFORMAL & FORMAL PMDA MEETING COSTS	
GRAND TOTAL (JPY) FOR INFORMAL & FORMAL PMDA MTGS	*

1.3. Timeline

*

1.4. Deliverables

- Informal PMDA Meeting Application Form including Executive Summary of Renazorb

- Presentation slide deck(s) for Informal PMDA and KOL meetings
- Meeting minutes for Informal PMDA and KOL meetings
- Formal PMDA Meeting Briefing Document and presentation slide deck of Renazorb
- PMDA Formal Meeting minutes

2. PROJECT TEAM

2.1. Project Team

The following proposed Ascent team members will be responsible for the respective functional roles related to the implementation of the Project listed below.

Name	Role	Hourly Rate
John Winebarger	Strategic Lead	*
Aki Tsutsui	Strategic Communications Support	*

Kazuhiro Kanmuri, PhD	Japan Development Lead	*
Noboru Sato, PhD	Regulatory Lead/ Non-Clinical Assessment	*
Yuki Kurai	Regulatory/ Project Management Lead	*
Mikako Miyako	Senior Regulatory Associate	*
Erika Zhang	Project Assistant	*
Key Opinion Leader (Approved by Unicycive)		*

2.2. Project Management

Overall responsibility for Services will reside with Mr. John Winebarger. In carrying out these responsibilities Mr. Winebarger will be supported by the team members listed above.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Registration Statement on Form S-1 of our report dated February 18, 2021, with respect to the financial statements of Unicycive Therapeutics, Inc. as of December 31, 2020 and 2019, and for the years then ended (which includes an explanatory paragraph related to the existence of substantial doubt about the Company's ability to continue as a going concern), and to the reference to us under the heading "Experts" included in this Registration Statement and accompanying prospectus on Form S-1.

/s/ Mayer Hoffman McCann P.C.
San Diego, California
May 21, 2021