Filed Pursuant to Rule 424(b)(4)
Registration No. 333-256367

5,000,000 Units
Common Stock and Warrants

This is an initial public offering of units of securities (the "Units) of Unicycive Therapeutics, Inc. No public market currently exists for our common stock. We are offering 5,000,000 Units at an initial public offering price of $5.00 per Unit.

Each Unit consists of (a) one share of our common stock and (b) four-fifth warrant (the "Warrants") to purchase one share of our common stock at an exercise price equal to $6.00, exercisable until the fifth anniversary of the issuance date, and subject to certain adjustment and cashless exercise provisions as described herein. The shares of our common stock and the Warrants are immediately separable and will be issued separately, but will be purchased together in this offering.

Our common stock has been approved for listing on the Nasdaq Capital Market under the symbol "UNCY." We do not intend to apply for any listing the Warrants on the Nasdaq Capital Market or any other securities exchange or nationally recognized trading system, and we do not expect a market to develop for the Warrants.

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 securities involves risks. See "Risk Factors" beginning on page 7.

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 Unit[2]	Total
Price to the public	$ 5.00	$ 25,000,000
Underwriting discounts and commissions	$ 0.35	$ 1,750,000
Proceeds to us (before expenses)[1]	$ 4.65	$ 23,250,000

(1) We refer you to "Underwriting" beginning on page 94 of this prospectus for additional information regarding underwriting compensation.

(2) The public offering corresponds to a public offering price per share of common stock of $4.99 and a public offering price per Warrant of $0.0125.

We have granted the underwriter an option, exercisable one or more times in whole or in part, to purchase up to 750,000 additional shares of common stock and/or Warrants to purchase up to an aggregate of 600,000 shares of common stock, in any combinations thereof, from us at $4.99 per share of common stock and $0.0125 per Warrant , less the underwriting discounts and commissions, for 45 days after the date of this prospectus to cover over-allotments, if any.

The underwriters expect to deliver the securities on or about July 15, 2021.

Sole Book-Running Manager

Roth Capital Partners

The date of this prospectus is July 13, 2021

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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 securities.

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

On June 21, 2021, we filed an Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware, which, among other things, effectuated a 1-for-4.3 (1:4.3) 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. All references to share and per share amounts of our common stock listed in this prospectus have been adjusted to give effect to the Reverse Stock Split. See "Description of Capital Stock" on page 86 for additional details on our Amended and Restated Certificate of Incorporation.

Amended and Restated Bylaws

Our Amended and Restated Bylaws have been adopted. See "Description of Capital Stock" on page 86 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

Securities offered by us	Each Unit consists of (a) one share of our common stock, par value $0.001 per share and (b) four-fifth Warrant to purchase one share of our common stock at an exercise price equal to $6.00, exercisable until the fifth anniversary of the issuance date.
Common stock to be outstanding immediately after this offering	14,496,854 shares (15,246,854 shares if the underwriters exercise their over-allotment option in full).
Over-allotment Option to purchase additional securities	We have granted the underwriter an option, exercisable one or more times in whole or in part, to purchase up to 750,000 additional shares of common stock and/or Warrants to purchase up to an aggregate of 600,000 shares of common stock, in any combinations thereof, from us at the public offering price per security, less the underwriting discounts and commissions, for 45 days after the date of this prospectus to cover over-allotments, if any. See "Underwriting" for additional information regarding the over-allotment option. Because the Warrants will not be listed on a national securities exchange or other nationally recognized trading market, the underwriters will be unable to satisfy any overallotment of shares and Warrants without exercising the underwriters' overallotment option with respect to the Warrants. As a result, the underwriters will exercise their overallotment option for all of the Warrants which are over-allotted, if any, at the time of the initial offering of the shares and the Warrants. However, because our common stock is publicly traded, the underwriters may satisfy some or all of the overallotment of shares of our common stock, if any, by purchasing shares in the open market and will have no obligation to exercise the overallotment option with respect to our common stock.
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $22,570,000, or approximately $26,057,000 if the underwriters exercise their over-allotment option in full, 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, the completion of Phase 1, and the start of 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, a unit purchase option entitling it to purchase a number of our securities equal to 5% of the securities sold in this offering at an exercise price of $6.25 per share. The unit purchase option 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 unit purchase option 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 94.
Risk factors	See "Summary of Risk Factors" and "Risk Factors" on page 5 and 7, respectively, and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in our securities.
Proposed Nasdaq Capital Market symbol	Our common stock has been approved for listing on the Nasdaq Capital Market under the symbol "UNCY." We do not intend to apply for any listing of the warrants on the Nasdaq Capital Market or any other securities exchange or nationally recognized trading system, and we do not expect a market for the warrants to develop.

The number of shares of our common stock to be outstanding after this offering is based on 8,763,491 shares of our common stock outstanding as of June 30, 2021 and the conversion of outstanding convertible notes into 733,363 shares of common stock, and excludes:

- 668,721 shares of common stock issuable upon exercise of outstanding options as of that date having a weighted average exercise price of $3.01 per share;
- 17,442 shares of our common stock reserved for future issuance under our 2018 Equity Incentive Plan;
- 1,296,977 shares of our common stock reserved for future issuance under our 2019 Stock Option Plan, and
- 1,302,326 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 additional 750,000 shares of common stock and/or 600,000 Warrants, to cover over-allotments, if any.
- a 1-for-4.3 reverse stock split of our common stock pursuant to which (i) every 4.3 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-4.3 basis, and (iii) the exercise price of each outstanding warrant or option to purchase common stock was proportionately increased on a 1-for-4.3 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;
- holders of our Warrants will have no rights as shareholders until they acquire shares of our common stock, if ever;
- we do not expect to pay dividends in the foreseeable future; and
- our Amended and Restated Certificate of Incorporation 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. All references to share and per share amounts of our common stock listed in this prospectus have been adjusted to give effect to the Reverse Stock Split.

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]	$ (0.27)	$ (0.27)	$ (0.04)	$ (0.11)
Weighted average common shares outstanding – basic and diluted[1]	8,120,012	8,499,687	8,462,350	8,576,422

(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]
	(unaudited)	(unaudited)	(unaudited)
Cash	$ 147	$ 147	$ 22,717
Working capital (deficit)	(3,402)	(612)	21,958
Total assets	513	513	23,083
Total liabilities	(3,915)	(1,125)	(1,125)
Accumulated deficit	(6,886)	(7,762)	(7,762)
Total stockholders' equity (deficit)	(3,402)	(612)	21,958

(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 733,363 shares of common stock .

(2) On a pro forma as adjusted basis to give further effect to our issuance and sale of 5,000,000 Units in this offering after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

An investment in our securities 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 our securities. 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 41.3% 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 Units 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 $3.49 per share, representing the difference between the initial public offering price of $5.00 per Unit and our pro forma net tangible book value per share as of March 31, 2021 of $1.51. Accordingly, should we be liquidated at our book value, you would not receive the full amount of your investment.

Holders of our Warrants will have no rights as shareholders until they acquire shares of our common stock, if ever.

If you acquire the Warrants to purchase shares of our common stock in this offering, you will have no rights with respect to our common stock until you acquire shares of such common stock upon exercise of your Warrants. Upon exercise of your Warrants, you will be entitled to exercise the rights of a holder of common stock only as to matters for which the record date occurs after the exercise date.

There is no public market for the Warrants being offered by us in this offering and an active trading market for the same is not expected to develop.

There is no established public trading market for the Warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for any listing of the Warrants offered hereby on the Nasdaq Capital Market or any other securities exchange or nationally recognized trading system. Without an active market, the liquidity of the Warrants will be severely limited.

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.

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

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

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

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

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

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

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

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

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our Amended and Restated Certificate of Incorporation, 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 this provision, if applicable.

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

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

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the preparation of our financial statements for the years ended December 31, 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 5,000,000 Units in this offering will be approximately $22.6 million, based on an initial public offering price of $5.00 per Unit, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option in full, we estimate that the net proceeds from this offering will be approximately $26.1 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 start of 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.

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 733,363 shares of common stock upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 5,000,000 Units at an initial public offering price of $5.00 per Unit, 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)
Cash	$ 147	$ 147	$ 22,717
Loan from stockholder	695	695	695
Convertible notes	2,790	-	-
Stockholders' equity (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, 8,747,889 shares issued and outstanding, actual; 9,496,854 shares issued and outstanding, pro forma; 14,496,854 shares issued and outstanding, pro forma as adjusted	9	10	15
Additional paid-in capital	3,475	7,140	29,705
Accumulated deficit	(6,886)	(7,762)	(7,762)
Total stockholders' equity (deficit)	(3,402)	(612)	21,958
Total capitalization	$ 83	$ 83	$ 22,653

The number of shares of our common stock to be outstanding after this offering is based on 8,747,889 shares of our common stock outstanding as of March 31, 2021 and excludes the following:

- 684,322 shares of common stock issuable upon exercise of outstanding options as of that date having a weighted average exercise price of $2.92 per share.
- 17,442 shares of common stock reserved for future issuance under our 2018 Equity Incentive Plan; and
- 1,296,977 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 1-for-4.3 (1:4.3) reverse stock split of our common stock; 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 ($0.39) per share of common stock, based on 8,747,889 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 733,363 shares of common stock upon the closing of this offering , our pro forma net tangible book value at March 31, 2021 would have been $(0.6 million), or ($0.06) per share of common stock.

After giving further effect to the sale of 5,000,000, Units in this offering at an initial public offering price of $5.00 per Unit, 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 $22.0 million, or $1.51 per share of common stock. This represents an immediate increase in pro forma as adjusted net tangible book value of $1.57 per share to existing stockholders and immediate dilution of $3.49 per share to new investors purchasing shares of common stock in this offering.

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

Initial public offering price per share		$ 5.00
Pro forma net tangible book value per share as of March 31, 2021	$ (0.06)	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors in this offering	1.57	
Pro forma as adjusted net tangible book value per share immediately after this offering		1.51
Dilution per share to new investors in this offering		$ 3.49

If the underwriters exercise their option in full, the pro forma as adjusted net tangible book value per share after giving effect to the offering would be $1.67 per share. This represents an increase in pro forma as adjusted net tangible book value of $1.73 per share to existing stockholders and dilution in pro forma as adjusted net tangible book value of $3.33 per share to new investors.

The number of shares of our common stock to be outstanding after this offering is based on 8,747,889 shares of our common stock outstanding as of March 31, 2021 and excludes the following:

- 684,322 shares of common stock issuable upon exercise of outstanding options as of that date having a weighted average exercise price of $2.92 per share.
- 17,442 shares of common stock reserved for future issuance under our 2018 Equity Incentive Plan; and
- 1,296,977 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 1-for-4.3 (1:4.3) reverse stock split of our common stock; 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 initial public offering price of $5.00 per Unit, 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	8,747,889	63.6%	$ 1,763,000	6.6%	$ 0.20
New investors	5,000,000	36.4%	25,000,000	93.4%	$ 5.00
Total	13,747,889	100.0%	$ 26,763,000	100.0%	

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 39.7% 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 60.3% 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. All references to share and per share amounts of our common stock listed in this prospectus have been adjusted to give effect to the Reverse Stock Split.

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 Unit.

Renazorb Purchase Agreement

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

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

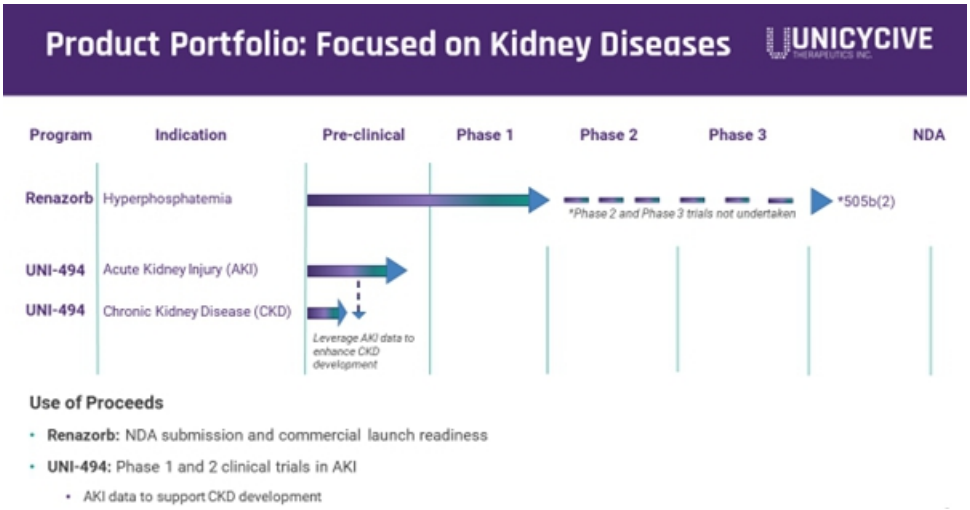
Ascent Master Services Agreement

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.

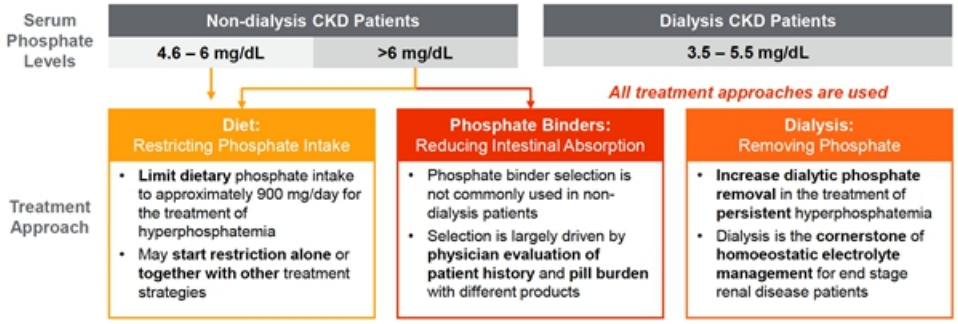


Figure 1: KDIGO guidelines recommend 3 main strategies

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.

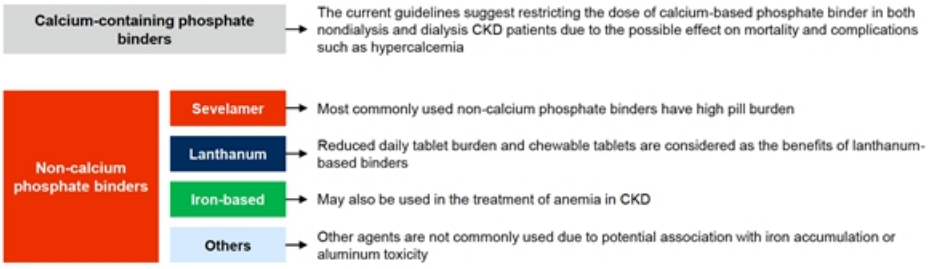


Figure 2: Phosphate Binders

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

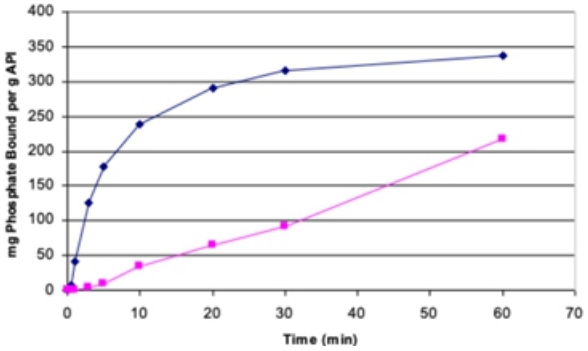
On September 20, 2018, we entered into an Assignment and Asset Purchase Agreement (the "Renazorb Purchase Agreement") with Spectrum Pharmaceuticals, Inc. ("Spectrum"), pursuant to which we purchased certain assets from Spectrum, including Spectrum's right, title, interest in and intellectual property 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 313,663 shares of common stock to Spectrum.

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

Mechanism of Action

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

In 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).

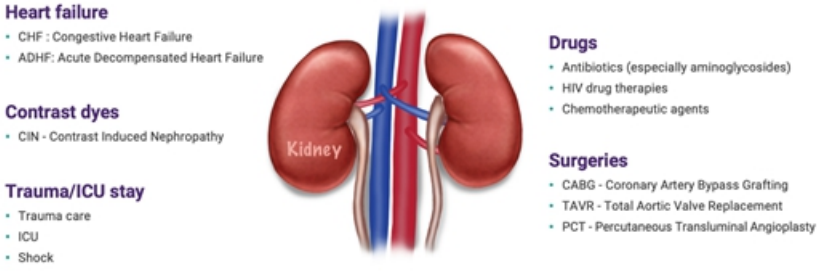


Figure 6: Adapted from Nature Review-Nephrology; Chawla LS et al. 2017

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.

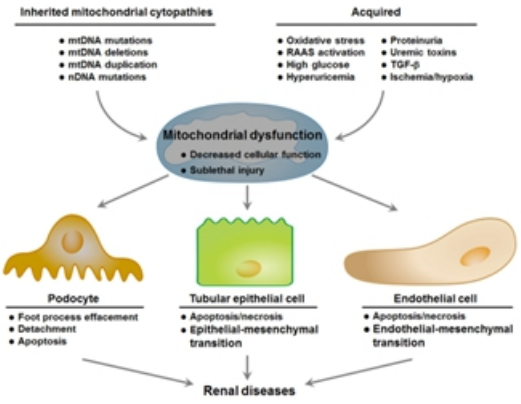
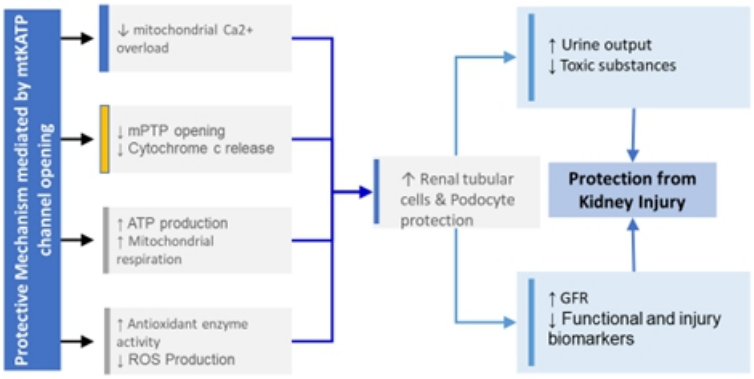


Figure 7: Che R, 2014: Mitochondria Dysfunction

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

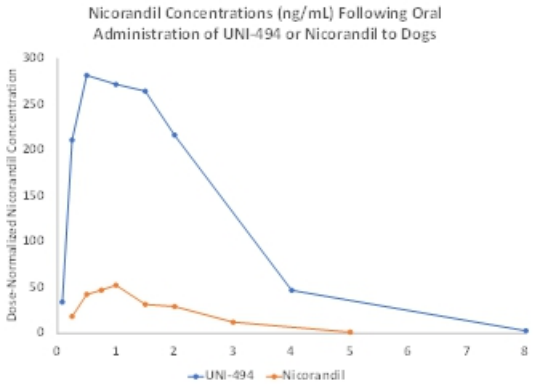
Despite these promising results, development of nicorandil for use in acute kidney injury has not been successfully pursued to date. Nicorandil possesses at least two features that may limit its use in this clinical setting. First, nicorandil has a short half-life in humans of approximately 1 hour, which 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, Ph.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, Ph.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

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code 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, contains 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 provides that we are authorized to indemnify our directors and officers to the fullest extent permitted by Delaware law. Our Amended and Restated Bylaws provides that we are required to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. Our Amended and Restated Bylaws 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 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 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, Ph.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*	189,923	135,659	0.013	07/25/2023
Pramod Gupta, Ph.D., Executive Vice President, Pharmaceutical and Business *Operations*	15,261	118,460	3.27	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 116,279 stock options, which shall vest over a period of three years from the date of grant. In addition, Dr. Gupta's employment agreement contains standard non-competition and non-solicitation provisions. Dr. Gupta is also eligible to receive additional equity-based compensation awards as the Company may grant from time to time. Dr. Gupta's employment agreement further provides for standard expense reimbursement, vacation time and other standard executive benefits.

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

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

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

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

Pramod Gupta Employment Agreement

On March 22, 2021 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 34,884 stock options, which shall vest over a period of three years from the date of grant. In addition, Mr. Gupta's employment agreement contains standard non-competition and non-solicitation provisions. Mr. Gupta is also eligible to receive additional equity-based compensation awards as the Company may grant from time to time. Mr. Gupta's employment agreement further provides for standard expense reimbursement, vacation time and other standard executive benefits.

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

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

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

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

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 465,116 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 348,837 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 348,837 to 1,767,442 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 have adopted a new comprehensive equity incentive plan, the 2021 Omnibus Equity Incentive Plan (the "2021 Plan").

Following the effective date of the 2021 Plan, no further awards may be issued under the 2018 Plan or the 2019 Plan (collectively, the "Prior Plans"). However, all awards under the Prior Plans that are outstanding as of the effective date of the 2021 Plan will continue to be governed by the terms, conditions and procedures set forth in the Prior Plans and any applicable award agreements.

Authorized Shares. A total of 5,600,000 shares of our common stock were originally reserved for issuance pursuant to the 2021 Plan. In connection with the Reverse Stock Split to be effectuated immediately before the effectiveness of the registration statement of which this prospectus forms a part, the number authorized shares of common stock issuable under the 2021 Plan will be adjusted to 1,302,326.

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 $100,000. 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 June 30, 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 June 30, 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 8,763,491 shares of common stock issued and outstanding as of June 30, 2021. Common Stock beneficially owned after the offering includes 733,363 shares of common stock issuable upon conversion of convertible notes in the aggregate principal amount of $2,388,000 issued between July 2020 and through May 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.

	Number of Shares Beneficially Owned	Percentage of Common Stock Beneficially Owned	
Name of Beneficial Owner	**Prior to Offering**	**Before Offering**	**After Offering**
Directors and Named Executive Officers:			
Shalabh Gupta, M.D.	5,780,678(1)	66.0	39.9
John Townsend	-	-	-
John Ryan, M.D., Ph.D.	66,619(2)	*	*
Sandeep Laumas, M.D.	114,293(3)	1.3	*
Pramod Gupta, Ph.D.	49,782(4)	*	*
Brigitte Schiller	-	-	-
All current named executive officers and directors as a group (6 persons)	6,011,372	68.1	41.3

* less than 1%

(1) Includes an aggregate of (i) 5,767,112 shares of common stock held by Dr. Gupta and/or entities controlled by Dr. Gupta; and (ii) 13,566 shares of common stock that will vest within 60 days of June 30, 2021.

(2) Includes an aggregate of (i) 58,140 shares of common stock held by Dr. Ryan; (ii) 7,995 shares of common stock underlying vested options to purchase shares of common stock; and (iii) 484 shares of common stock that will vest within 60 days of June 30, 2021.

(3) Includes an aggregate of (i) 105,814 shares of common stock held by Dr. Laumas and/or entities controlled by Dr. Laumas; (ii) 7,995 shares of common stock underlying vested options to purchase shares of common stock; and (iii) 484 shares of common stock that will vest within 60 days of June 30, 2021.

(4) Includes an aggregate of (i) 44,210 shares of common stock underlying vested options to purchase shares of common stock and (ii) 5,572 shares of common stock that will vest within 60 days of June 30, 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 June 30, 2021, there were 8,763,491 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 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

On June 21, 2021 we filed our Amended and Restated Certificate of Incorporation which effectuated a 1-for-4.3 (1:4.3) 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. All references to share and per share amounts of our common stock listed in this prospectus have been adjusted to give effect to the Reverse Stock Split.

Units Offered Hereby

We are offering 5,000,000 Units at a fixed price of $5.00 per Unit, the midpoint of the range set forth on the cover page of this prospectus. Each Unit consists of (a) one share of our common stock and (b) four-fifth warrant to purchase one share of our common stock at an exercise price equal to $6.00 per share, exercisable until the fifth anniversary of the issuance date, and subject to certain adjustment and cashless exercise provisions as described herein.

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.

Warrant Agent

The Warrants will be issued in registered form under a warrant agent agreement (the "Warrant Agent Agreement") between us and our warrant agent, Philadelphia Stock Transfer, Inc. (the "Warrant Agent"). The material provisions of the warrants are set forth herein and a copy of the Warrant Agent Agreement has been filed as an exhibit to the Registration Statement on Form S-1, of which this prospectus forms a part. The Company and the Warrant Agent may amend or supplement the Warrant Agent Agreement without the consent of any holder for the purpose of curing any ambiguity, or curing, correcting or supplementing any defective provision contained therein or adding or changing any other provisions with respect to matters or questions arising under the Warrant Agent Agreement as the parties thereto may deem necessary or desirable and that the parties determine, in good faith, shall not adversely affect the interest of the Warrant holders. All other amendments and supplements to the Warrant Agent Agreement shall require the vote or written consent of holders of at least 50.1% of the Warrants.

Warrants Offered Hereby

The Warrants entitle the registered holder to purchase one share of our common stock at a price equal to $6.00 per share, subject to adjustment as discussed below, terminating at 5:00 p.m., New York City time, on the fifth (5^{th}) anniversary of the date of issuance.

The exercise price and number of shares of common stock issuable upon exercise of the Warrants may be adjusted in certain circumstances, including in the event of a stock dividend, extraordinary dividend on or recapitalization, reorganization, merger or consolidation.

The Warrants may be exercised upon surrender of the warrant certificate on or prior to the expiration date at the offices of the Warrant Agent, with the exercise form attached to the warrant certificate completed and executed as indicated, accompanied by full payment of the exercise price, by certified or official bank check payable to us, for the number of warrants being exercised. The Warrant holders do not have the rights or privileges of holders of common stock and any voting rights until they exercise their Warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

No Warrants will be exercisable for cash unless at the time of the exercise a prospectus or prospectus relating to common stock issuable upon exercise of the Warrants is current and the common stock has been registered or qualified or deemed to be exempt under the securities laws of the state of residence of the holder of the warrants. Under the terms of the Warrant Agent Agreement, we have agreed to use our best efforts to maintain a current prospectus or prospectus relating to common stock issuable upon exercise of the Warrants until the expiration of the Warrants. Additionally, the market for the Warrants may be limited if the prospectus or prospectus relating to the common stock issuable upon exercise of the Warrants is not current or if the common stock is not qualified or exempt from qualification in the jurisdictions in which the holders of such Warrants reside. In no event will the registered holders of a Warrant be entitled to receive a net-cash settlement in lieu of physical settlement in shares of our common stock.

No fractional shares of common stock will be issued upon exercise of the Warrants. If, upon exercise of the Warrants, a holder would be entitled to receive a fractional interest in a share, we will, upon exercise, round down to the nearest whole number the number of shares of common stock to be issued to the Warrant holder. If multiple Warrants are exercised by the holder at the same time, we will aggregate the number of whole shares issuable upon exercise of all the Warrants.

The price of the Warrants has been arbitrarily established by us and the Underwriters after giving consideration to numerous factors, including but not limited to, the pricing of the Units in this offering. No particular weighting was given to any one aspect of those factors considered. We have not performed any method of valuation of the Warrants.

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, 17,442 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, 1,296,977 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 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, or (iv) any action asserting a claim against us, our directors, officers, employees or agents governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. This exclusive forum provision would not apply to suits brought to enforce any liability or duty created by the Securities Act, the Exchange Act, or other federal securities laws or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our Amended and Restated Certificate of Incorporation, contains a federal forum provision which provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock are deemed to have notice of and consented to 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 this 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 authorizes 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 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 provides 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 120^{th} 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 10^{th} 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

Our common stock has been approved for listing on the Nasdaq Capital Market under the symbol "UNCY."

We do not intend to apply for any listing of the warrants on the Nasdaq Capital Market or any other securities exchange or nationally recognized trading system, and we do not expect a market for the warrants to develop.

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 been approved, subject to notice of issuance, 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 Units 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 Units
Roth Capital Partners, LLC	5,000,000
Total	5,000,000

The underwriting agreement will provide that the underwriters are obligated to purchase all of the shares of common stock and warrants offered by this prospectus, other than those covered by the over-allotment option, if any shares of common stock and warrants are purchased. The underwriters are offering the Units 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 Units 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 $0.1750 per Unit. After completion of the public offering of the Units, 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 750,000 shares of common stock and/or additional Warrants to purchase up to 600,000 shares of common stock in any combination thereof on the same terms as the other shares and Warrants 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 Unit, less the amount paid by the underwriters to us per Unit. The underwriting discount was determined through an arms' length negotiation between us and the underwriters.

We have agreed to sell the Units to the underwriters at the initial offering price of $4.65 per Unit, which represents the initial public offering price of the Units 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 750,000 additional shares of common stock and/or additional Warrants to purchase up to 600,000 shares of common stock.

	Per Unit	Total Without Over-Allotment Option	Total With Over Allotment Option
Public offering price	$ 5.00	$ 25,000,000	$ 28,750,000
Underwriting discounts and commissions	$ 0.35	$ 1,750,000	$ 2,012,500
Net proceeds to us	$ 4.65	$ 23,250,000	$ 26,737,500

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 $70,000. 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 $600,000.

Unit Purchase Option

Upon the closing of this offering, we have agreed to sell to the underwriters a unit purchase option to purchase up to 5% of the number of securities sold in this offering. The unit purchase option will have an exercise price equal to 125% of the public offering price of the combination of shares and warrants set forth on the cover page of this prospectus (or $6.25 per share and accompanying warrant), subject to standard anti-dilution adjustments for share splits and similar transactions. The unit purchase option 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 unit purchase option is also exercisable on a cashless basis. The unit purchase option has been deemed compensation by FINRA and is 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 unit purchase option or the securities underlying the unit purchase option, 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 unit purchase option and the underlying securities have been registered in the registration statement of which this prospectus forms a part, we have also agreed to provide holders of the unit purchase option one demand registration right and unlimited "piggy-back" registration rights with respect to the securities underlying the unit purchase option on only one occasion to register all of such securities 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 unit purchase option, 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 unit purchase option, 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 Units 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 Units 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

Our common stock has been approved for listing on the Nasdaq Capital Market under the symbol “UNCY”.

We do not intend to apply for any listing of the warrants on the Nasdaq Capital Market or any other securities exchange or nationally recognized trading system, and we do not expect a market for the warrants to develop.

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 Units and the common stock and warrants underlying the Units 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 securities 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 securities, 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, except for the effects of the stock split as described in Note 2, as to which the date is June 21, 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); 8,456,179 shares issued and outstanding at December 31, 2019, 8,514,070 shares issued and outstanding at December 31, 2020, and 8,747,889 shares issued and outstanding at March 31, 2021 (unaudited)	8	9	9
Additional paid-in capital	2,766	3,242	3,475
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	$ (0.27)	$ (0.27)	$ (0.04)	$ (0.11)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	8,120,012	8,499,687	8,462,350	8,576,422

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	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at December 31, 2018	7,851,751	$ 8	-	$ -	$ 279	$ (1,493)	$ (1,206)
Net loss	-	-	-	-	-	(2,165)	(2,165)
Issuance of common stock for cash	288,059	-	-	-	1,166	-	1,166
Conversion of convertible notes into common stock	269,557	-	-	-	1,102	-	1,102
Issuance of common stock for anti-dilution clause	34,830	-	-	-	145	-	145
Issuance of common stock in settlement of accounts payable	11,982	-	-	-	50	-	50
Stock-based compensation expense	-	-	-	-	24	-	24
Balance at December 31, 2019	8,456,179	8	-	-	2,766	(3,658)	(884)
Net loss	-	-	-	-	-	(2,264)	(2,264)
Issuance of common stock for cash	33,263	1	-	-	140	-	141
Issuance of common stock for anti-dilution clause	24,628	-	-	-	104	-	104
Stock-based compensation expense	-	-	-	-	232	-	232
Balance at December 31, 2020	8,514,070	$ 9	-	$ -	$ 3,242	$ (5,922)	$ (2,671)

	Common Stock		Preferred stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at December 31, 2019	8,456,179	$ 8	-	$ -	$ 2,766	$ (3,658)	$ (884)
Net loss (unaudited)	-	-	-	-	-	(344)	(344)
Issuance of common stock for cash (unaudited)	11,862	-	-	-	50	-	50
Issuance of common stock for anti-dilution clause (unaudited)	475	-	-	-	2	-	2
Stock-based compensation expense (unaudited	-	-	-	-	31	-	31
Balance at March 31, 2020 (unaudited)	8,468,516	$ 8	-	$ -	$ 2,849	$ (4,002)	$ (1,145)
Balance at December 31, 2020	8,514,070	$ 9	-	$ -	$ 3,242	$ (5,922)	$ (2,671)
Net loss (unaudited)	-	-	-	-	-	(964)	(964)
Issuance of common stock for exercise of options (unaudited)	233,819	-	-	-	31	-	31
Stock-based compensation expense (unaudited)	-	-	-	-	202	-	202
Balance at March 31, 2021 (unaudited)	8,747,889	$ 9	-	$ -	$ 3,475	$ (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").

All common share amounts and per share amounts have been adjusted to reflect a 1-for-4.3 reverse stock split of the Company's common stock to be effected immediately prior to the effectiveness of the Company's registration statement on Form S-1 in connection with its initial public offering.

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. All common share amounts and per share amounts have been adjusted to reflect a 1-for-4.3 reverse stock split of the Company's common stock to be effected immediately prior to the effectiveness of the Company's registration statement on Form S-1 in connection with its initial public offering.

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 313,663 shares of common stock to Spectrum valued at approximately $4,000 which represented four percent of the Company on a fully-diluted basis at the date of the execution of the Spectrum Agreement. The Spectrum Agreement has an anti-dilution provision, which provides that Spectrum maintain its ownership interest in the Company at 4% of the Company's shares on a fully-diluted basis. Fully-diluted shares of common stock for purposes of the Renazorb Purchase Agreement assumes conversion of any security convertible into or exchangeable or exercisable for common stock or any combination thereof, including any common stock reserved for issuance under a stock option plan, restricted stock plan, or other equity incentive plan approved by the Board of Directors of the Company immediately following the issuance of additional shares of the Company's common stock (but prior to the issuance of any additional shares of common stock to Spectrum). Spectrum's ownership shall not be subject to dilution until the earlier of thirty-six months from the first date the Company's stock trades on a public market, or the date upon which the Company attains a public market capitalization of at least $50 million. As part of the anti-dilution clause, the Company issued 149,762 and 105,897 shares of common stock during the years ended December 31, 2019 and 2020, respectively. The Company recognized $145,000 and $104,000 for the years ended December 31, 2019 and 2020, respectively, as research and development expenses as cost to issue those shares. 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 62,181 shares of the Company's common stock, valued at $0.013 per share, to Globavir's stockholders as payment for Globavir's services and shared costs rendered on behalf of the Company in 2017, which were issued in 2018.

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 383,721 stock options and the Company received $119,000 in proceeds. A portion of these options were exercised early (prior to vesting), and as of March 31, 2021, 149,903 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 233,818 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 11,860 shares to investors in exchange of cash at $4.21 per share.

During the year ended December 31, 2020, the Company issued 33,260 shares to investors in exchange of cash at $4.21 per share and 24,627 shares to Spectrum following its anti-dilution provision (Note 3).

During 2019, the Company issued 288,050 shares to investors for a total of $1,166,000 with prices ranging from $3.57 to $4.21 per share, 269,550 shares upon conversion of its convertible notes (Note 5), 34,828 shares to Spectrum following its anti-dilution provision (Note 3) and 11,982 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, 465,116 shares are authorized for issuance and 17,442 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, 232,558 shares were authorized for issuance and 75,581 shares were available for future grant under the 2019 Plan. On April 6, 2020 the Company increased the shares authorized for issuance to 348,837 shares total. On February 17, 2021, the Company increased the shares authorized for issuance to 1,767,442 shares total. As of March 31, 2021, 1,296,977 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	447,674	0.013	9.66	1,284
Options granted	156,977	3.27		
Outstanding, December 31, 2019	604,651	0.86	8.56	2,029
Options granted	181,395	3.27		
Outstanding, December 31, 2020	786,047	1.42	8.28	2,201
Options granted	132,093	7.01		
Options exercised	(233,818)	0.13		
Outstanding, March 31, 2021	684,322	2.92	7.73	2,790
Shares vested and exercisable as of December 31, 2019	162,307	$ -	8.66	$ 2,029
Shares vested and exercisable as of December 31, 2020	311,443	$ 0.52	7.85	$ 1,151
Shares vested and exercisable as of March 31, 2021	141,898	$ 1.94	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	8,120,012	8,499,687	8,462,350	8,576,422
Net loss per share attributable to common stockholders, basic and diluted	$ (0.27)	$ (0.27)	$ (0.04)	$ (0.11)

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	604,651	786,047	786,047	684,322
Total	604,651	786,047	786,047	684,322

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.

On July 13, 2021, the Company entered into an underwriting agreement with Roth Capital Partners, pursuant to which the Company issued and sold, in an underwritten initial public offering, 5,000,000 units at a public offering price per unit of $5.00. Each unit consists of one share of common stock and four-fifths of a warrant to purchase one share of common stock. The warrants have an exercise price of $6.00 per share and are exercisable for a period of five years after the issuance date. In addition, the Company has granted the underwriters a 45-day option to purchase up to an additional 750,000 shares of its common stock and/or warrants to purchase up to an additional 600,000 shares of its common stock, at the initial public offering price, less the underwriting discounts and commissions.

5,000,000 Units
Common Stock
Warrants

Prospectus

July 13, 2021

Sole Book-Running Manager

Roth Capital Partners

Until August 7, 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.