

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

FORM 10-Q

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

For the quarterly period ended **June 30, 2021**

OR

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

For the transition period from ____ to ____

Commission file number: **001-40582**

UNICYCIVE THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

2834

(Primary Standard Industrial
Classification Code Number)

81-3638692

(I.R.S. Employer
Identification Number)

5150 El Camino Real, Suite A-32

Los Altos, CA 94022

(650) 351-4495

(Address and telephone number of principal executive offices)

Not applicable

(Former name, former address, and former fiscal year, if changed since last report)

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

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

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

As of August 16, 2021, there were 14,508,063 shares of the Company's common stock, par value \$0.001 per share, issued and outstanding.

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FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q for the three-month period ended June 30, 2021 contains “forward-looking statements” within the meaning of the Securities Act of 1933, as amended (the “Securities Act”), and the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These forward-looking statements contain information about our expectations, beliefs or intentions regarding our product development and commercialization efforts, business, financial condition, results of operations, strategies or prospects, and other similar matters. These forward-looking statements are based on management’s current expectations and assumptions about future events, which are inherently subject to uncertainties, risks and changes in circumstances that are difficult to predict. These statements may be identified by words such as “expects,” “plans,” “projects,” “will,” “may,” “anticipates,” “believes,” “should,” “intends,” “estimates,” and other words of similar meaning.

Actual results could differ materially from those contained in forward-looking statements. Many factors could cause actual results to differ materially from those in forward-looking statements, including those matters discussed below. Readers are urged to read the risk factors set forth in the Company’s recent filings with the U. S. Securities and Exchange Commission (the “SEC”). These filings are available at the SEC’s website (www.sec.gov).

Other unknown or unpredictable factors that could also adversely affect our business, financial condition and results of operations may arise from time to time. Given these risks and uncertainties, the forward-looking statements discussed in this report may not prove to be accurate. Accordingly, you should not place undue reliance on these forward-looking statements, which only reflect the views of the Company’s management as of the date of this report. We undertake no obligation to update or revise forward-looking statements to reflect changed assumptions, the occurrence of unanticipated events or changes to future operating results or expectations, except as required by law.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Unicycive Therapeutics, Inc.

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

	As of December 31, 2020	As of June 30, 2021 (unaudited)
Assets		
Current assets:		
Cash	\$ -	\$ 1
Prepaid related party service fee	-	38
Deferred offering costs	200	864
Prepaid expenses and other current assets	4	10
Total current assets	<u>204</u>	<u>913</u>
Total assets	<u>\$ 204</u>	<u>\$ 913</u>
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 184	\$ 357
Related party service fee payable	9	-
Accrued liabilities	168	658
Convertible notes	1,528	3,199
Loan from stockholder	967	901
Government loan	19	-
Total current liabilities	<u>2,875</u>	<u>5,115</u>
Total liabilities	2,875	5,115
Commitments and contingencies (Note 7)		
Stockholders' deficit:		
Preferred stock: \$0.001 par value per share—10,000,000 shares authorized at December 31, 2020 and June 30, 2021 (unaudited); no shares issued and outstanding at December 31, 2020 and June 30, 2021 (unaudited)	\$ -	\$ -
Common stock, \$0.001 par value per share – 200,000,000 shares authorized at December 31, 2020 and June 30, 2021 (unaudited); 8,514,070 shares issued and outstanding at December 31, 2020, and 8,771,290 shares issued and outstanding at June 30, 2021 (unaudited)	9	9
Additional paid-in capital	3,242	3,775
Accumulated deficit	<u>(5,922)</u>	<u>(7,986)</u>
Total stockholders' deficit	<u>(2,671)</u>	<u>(4,202)</u>
Total liabilities and stockholders' deficit	<u>\$ 204</u>	<u>\$ 913</u>

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2021	2020	2021
Operating expenses:				
Research and development	\$ 182	\$ 493	\$ 329	\$ 942
General and administrative	154	286	349	568
Total operating expenses	<u>336</u>	<u>779</u>	<u>678</u>	<u>1,510</u>
Loss from operations	(336)	(779)	(678)	(1,510)
Other expenses:				
Interest expense	(2)	(321)	(4)	(573)
Gain on extinguishment of debt	-	-	-	19
Total other expenses	<u>(2)</u>	<u>(321)</u>	<u>(4)</u>	<u>(554)</u>
Net loss	\$ (338)	\$ (1,100)	\$ (682)	\$ (2,064)
Net loss per share, basic and diluted	\$ (0.04)	\$ (0.13)	\$ (0.08)	\$ (0.24)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	<u>8,483,382</u>	<u>8,771,290</u>	<u>8,472,866</u>	<u>8,677,497</u>

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.

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

	Common Stock		Preferred stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 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)
Net loss (unaudited)	-	-	-	-	-	(338)	(338)
Issuance of common stock for cash (unaudited)	21,401	1	-	-	91	-	92
Issuance of common stock for anti-dilution clause (unaudited)	6,624	-	-	-	28	-	28
Stock-based compensation expense (unaudited)	-	-	-	-	60	-	60
Balance at June 30, 2020 (unaudited)	8,496,541	\$ 9	-	\$ -	\$ 3,028	\$ (4,340)	\$ (1,303)
	Common Stock		Preferred stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
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)
Net loss (unaudited)	-	-	-	-	-	(1,100)	(1,100)
Issuance of common stock for exercise of options (unaudited)	23,401	-	-	-	6	-	6
Stock-based compensation expense (unaudited)	-	-	-	-	294	-	294
Balance at June 30, 2021 (unaudited)	8,771,290	\$ 9	-	\$ -	\$ 3,775	\$ (7,986)	\$ (4,202)

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.

Statements of Cash Flows
(in thousands)
(Unaudited)

	Six Months Ended June 30, 2020	Six Months Ended June 30, 2021
Cash flows from operating activities		
Net loss	\$ (682)	\$ (2,064)
Adjustments to reconcile net loss to net cash used in operating activities:		
R&D Expense for issuance of common stock for anti-dilution clause	30	-
Stock-based compensation expense	91	496
Convertible debt discount amortization	-	447
Convertible debt non-cash interest	-	127
Gain on extinguishment of debt	-	(19)
Deferred compensation to CEO	262	157
Changes in assets and liabilities:		
Prepaid expense and other current assets	(23)	(7)
Related party service fee receivable	-	(38)
Accounts payable and accrued liabilities	112	20
Related party service fee payable	(5)	(9)
Net cash used in operating activities	<u>(215)</u>	<u>(890)</u>
Cash flows from financing activities		
Issuance of common stock	142	-
Proceeds from loan from stockholder	40	237
Proceeds from convertible notes	-	1,098
Repayment of loan from stockholder	-	(460)
Deferred offering costs	-	(103)
Proceeds from exercise of options	-	119
Proceeds from government loan	19	-
Net cash provided by financing activities	<u>201</u>	<u>891</u>
Net (decrease) increase in cash	<u>(14)</u>	<u>1</u>
Cash at the beginning of the period	<u>15</u>	<u>-</u>
Cash at the end of the period	<u>\$ 1</u>	<u>\$ 1</u>
Supplemental cash flow information		
Deferred offering costs included in accrued liabilities	\$ -	\$ 519
Cash paid for income taxes	\$ 1	\$ -

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.

Notes to the Financial Statements (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 June 30, 2021 and December 31, 2020, the Company had an accumulated deficit of \$8.0 million and \$5.9 million, respectively.

As a result of its initial public offering (“IPO”), on July 13, 2021 the Company began trading on the Nasdaq Capital Market under the symbol “UNCY”, and on July 15, 2021 received approximately \$23,212,000 in net proceeds after deducting the underwriting discounts and commissions and estimated offering expenses. The Company intends to use the net proceeds from the IPO to complete pre-clinical and clinical studies, submit regulatory filings to the FDA, and for general and corporate purposes, including hiring additional management and conducting market research and other commercial planning.

The Company expects to continue incurring losses for the foreseeable future and will be required to raise additional capital in the future to complete its planned clinical trials, pursue product development initiatives and penetrate markets for the sale of its products. Management believes that the Company will continue to have access to capital resources through possible equity offerings, debt financings, corporate collaborations or other means. From January 2021 through May 2021, the Company received an aggregate of \$1.1 million upon the issuance of convertible notes. These funds were used primarily to settle outstanding accounts payable as well as \$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, given the Company’s nominal cash balance of \$1,000 as of June 30, 2021, and after including the net proceeds received on July 15, 2021 as a result of the Company’s IPO, the Company believes that it has sufficient resources to continue operations for at least one year after the date that these financial statements are available to be issued.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the periods presented. Management believes that these estimates and assumptions are reasonable; however, actual results may differ and could have a material effect on future results of operations and financial position. Significant items subject to such estimates and assumptions include 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 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 IPO, which occurred on July 15, 2021. There were \$0.2 million and \$0.9 million of deferred offering costs capitalized as of December 31, 2020 and June 30, 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, 2020 and June 30, 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 at June 30, 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 that was effectuated on June 21, 2021.

Recent Accounting Pronouncements

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

In August 2020, the FASB issued ASU 2020-06, Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity, which simplifies the accounting for convertible instruments. ASU 2020-06 eliminates certain models that require separate accounting for embedded conversion features. Additionally, among other changes, the guidance eliminates certain of the conditions for equity classification for contracts in an entity’s own equity. The guidance also requires entities to use the if-converted method for all convertible instruments in the diluted earnings per share calculation and include the effect of share settlement for instruments that may be settled in cash or shares, except for certain liability-classified share-based payment awards. This guidance is effective for the Company beginning in the first quarter of 2022 and must be applied using either a modified or full retrospective approach. Early adoption is permitted, but no earlier than annual periods beginning after December 15, 2020. The Company is currently evaluating the impact this guidance will have on its financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU requires a lessee to recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the leases with a term of greater than 12 months. This ASU is effective for the Company’s fiscal years beginning after December 15, 2021, with early adoption permitted. The Company has adopted this standard effective as of January 1, 2019. The Company chose to adopt 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 (20th) 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, 2020 and June 30, 2021 consisted of the following (in thousands):

	<u>As of December 31, 2020</u>	<u>As of June 30, 2021 (unaudited)</u>
Trade accounts payable	\$ 183	\$ 334
Credit card liability	1	23
Total	<u>\$ 184</u>	<u>\$ 357</u>

5. Debt

Convertible Notes

In January through May 2021, the Company issued convertible notes (the “2021 Notes”) in the aggregate principal amount of approximately \$1,098,000. The 2021 Notes bear interest at a rate of 12% per annum, payable at maturity, and mature between January and May, 2022. The 2021 Notes shall automatically convert into shares of the Company’s common stock upon the closing of a financing pursuant to which the Company receives gross proceeds of at least \$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 June 30, 2021, unpaid and accrued interest of \$49,000 as well as debt discount accretion expense of approximately \$172,000 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 June 30, 2021, unpaid and accrued interest of \$130,000 as well as debt discount accretion expense of approximately \$460,000 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 six months ended June 30, 2021.

6. Related Party Transactions

Loan from Chief Executive Officer and Stockholder

As of June 30, 2021 and December 31, 2020, the current liability loan from a stockholder of approximately \$901,000 and \$967,000, 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, 2020, \$9,000 was payable to Globavir for such service fees. As of June 30, 2021, \$38,000 was prepaid to Globavir for such service fees. Amounts incurred by the Company under the Service Agreement were \$30,000, \$30,000, \$60,000 and \$60,000 for the three and six months ended June 30, 2020 and June 30, 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 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. The Company accrued the \$150,000 advisory fee in June 2021, and the fee is recorded as a deferred offering cost on the accompanying balance sheet.

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 following the July 15, 2021 completion of the Company's 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 six months ended June 30, 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 June 30, 2021, 126,501 of the options remained unvested. Proceeds received related to the unvested options of \$82,000 at June 30, 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 vested portion of the exercises was 257,220 shares at June 30, 2021.

During the six months ended June 30, 2020, the Company issued 33,263 shares to investors in exchange of cash at \$4.21 per share.

During the year ended December 31, 2020, the Company issued 33,263 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).

Voting Rights of Common Stock

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

Preferred Stock

As of December 31, 2020 and June 30, 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, 2020 and June 30, 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 June 30, 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 six months ended June 30, 2021:

	Number of Shares Underlying Outstanding Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2020	786,047	1.42	8.28	2,201
Options granted	132,093	7.01		
Options exercised	(257,219)	0.12		
Outstanding, June 30, 2021	660,921	3.03	7.61	2,631
Shares vested and exercisable as of June 30, 2021	215,599	\$ 2.94	8.19	\$ 877

The grant date fair value of options granted during the six months ended June 30, 2021 was \$0.7 million.

As of June 30, 2021, the unrecognized compensation cost related to outstanding stock options was \$1.2 million, which is expected to be recognized as expense over approximately 2.8 years.

The Company has recorded stock-based compensation expense, allocated by functional cost as follows for the three and six months ended June 30, 2020 and 2021 (in thousands):

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2021	2020	2021
Research and development	\$ 43	\$ 271	\$ 60	\$ 456
General and administrative	17	23	31	40
Total stock-based compensation	\$ 60	\$ 294	\$ 91	\$ 496

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 year ended December 31, 2020 and for the six months ended June 30, 2020 and 2021:

	Six Months Ended	
	June 30,	
	2020	2021
Expected volatility	114.00%	104.00 – 105.00%
Risk-free interest rate	0.44 - 0.51%	0.92%
Dividend yield	-%	-%
Expected term	6.25 years	5.13 – 6.25 years

10. 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):

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2021	2020	2021
Numerator:				
Net loss	\$ (338)	\$ (1,100)	\$ (682)	\$ (2,064)
Denominator:				
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	8,483,382	8,771,290	8,472,866	8,677,497
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.04)	\$ (0.13)	\$ (0.08)	\$ (0.24)

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:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2021	2020	2021
Options to purchase common stock	748,837	660,921	748,837	660,921
Total	748,837	660,921	748,837	660,921

11. Subsequent Events

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. On July 15, 2021, the underwriters exercised their option to purchase warrants for an additional 600,000 shares of common stock, and the Company received gross proceeds of \$7,500 for the exercise.

As a result of its initial public offering (“IPO”), on July 13, 2021 the Company began trading on the Nasdaq Capital Market under the symbol “UNCY”, and on July 15, 2021 received approximately \$23,212,000 in net proceeds after deducting the underwriting discounts and commissions and estimated offering expenses. The Company intends to use the net proceeds from the IPO to complete pre-clinical and clinical studies, submit regulatory filings to the FDA, and for general and corporate purposes, including hiring additional management and conducting market research and other commercial planning.

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

On July 15, 2021, in connection with the completion of the Company’s IPO, the Company adopted a new comprehensive equity incentive plan, the 2021 Omnibus Equity Incentive Plan (the “2021 Plan”). Following the effective date of the 2021 Plan, no further awards may be issued under the 2018 Plan or the 2019 Plan (collectively, the “Prior Plans”). However, all awards under the Prior Plans that are outstanding as of the effective date of the 2021 Plan will continue to be governed by the terms, conditions and procedures set forth in the Prior Plans and any applicable award agreements. A total of 1,302,326 shares of common stock are reserved for issuance pursuant to the 2021 Plan. The 2021 Plan provides for the issuance of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards.

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

During July 2021, in connection with the completion of the Company’s IPO, Shalabh Gupta, our Chief Executive Officer, was paid approximately \$463,000 for previously earned deferred compensation and approximately \$219,000 for previously earned bonus amounts. Dr. Gupta was also repaid \$216,000 for previous loans made to the Company.

In connection with the completion of the Company’s IPO, additional shares of common stock will be issued to Spectrum Pharmaceuticals, Inc., in September of 2021. The Company’s agreement with Spectrum contains an anti-dilution clause such that Spectrum maintains an ownership interest in the Company at 4% of the Company’s shares on a fully-diluted basis. The anti-dilution clause automatically expired after July 13, 2021 due to the Company attaining a market capitalization of more than \$50 million as a result of the IPO.

ITEM 2. 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 quarterly report and in our previously filed registration statement on Form S-1. 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 quarterly report. See “Information Regarding Forward-Looking Statements.” All amounts in this report are in U.S. dollars, unless otherwise noted.

Overview

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

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

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

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

Since our formation we have devoted substantially all of our resources to developing our product candidates. We have incurred significant operating losses to date. Our net losses were \$0.3 million, \$1.1 million, \$0.7 million and \$2.1 million for the three and six months ended June 30, 2020 and 2021, respectively. As of December 31, 2020 and June 30, 2021, we had an accumulated deficit of \$5.9 million and \$8.0 million, respectively. 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. As a result of its initial public offering (“IPO”), on July 13, 2021 we began trading on the Nasdaq Capital Market under the symbol “UNCY”, and on July 15, 2021 we received approximately \$23,212,000 in net proceeds after deducting the underwriting discounts and commissions and estimated offering expenses.

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 converted into common stock upon consummation of our initial public offering at 70% of the public offering price per Unit.

As a result of its initial public offering (“IPO”), on July 13, 2021 the Company began trading on the Nasdaq Capital Market under the symbol “UNCY”, and on July 15, 2021 received approximately \$23,212,000 in net proceeds after deducting the underwriting discounts and commissions and estimated offering expenses.

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

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 June 30, 2020 and 2021

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

	Three Months Ended June 30,		Change	% Change
	2020	2021		
Operating expenses:				
Research and development	\$ 182	\$ 493	\$ 311	171%
General and administrative	154	286	132	86%
Total operating expenses	<u>336</u>	<u>779</u>	<u>443</u>	<u>132%</u>
Loss from operations	(336)	(779)	(443)	132%
Other income (expenses):				
Interest expense	(2)	(321)	(319)	15,950%
Gain on extinguishment of debt	-	-	-	0%
Total other income (expenses)	<u>(2)</u>	<u>(321)</u>	<u>(319)</u>	<u>15,950%</u>
Net loss	<u>\$ (338)</u>	<u>\$ (1,100)</u>	<u>\$ (762)</u>	<u>225%</u>

Research and Development Expenses

Research and development expenses increased by approximately \$311,000, or 171%, from the three months ended June 30, 2020 to the three months ended June 30, 2021. The increase in research and development expenses was primarily due to an increase in stock compensation expense of \$227,000. In addition, development costs increased \$84,000 due to product formulation and consulting services in the current period.

General and Administrative Expenses

General and administrative expenses increased by \$132,000, or 86%, from the three months ended June 30, 2020 to the three months ended June 30, 2021 primarily due to an increase in accounting and professional services costs of \$113,000. In addition, labor costs increased \$12,000 and stock compensation costs increased \$7,000.

Other Income (Expenses)

Other income (expenses) increased by \$319,000, or 15,950% from the three months ended June 30, 2020 to the three months ended June 30, 2021. The increase was due primarily to interest expense on outstanding convertible notes.

Comparison of the Six Months Ended June 30, 2020 and 2021

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

	Six Months Ended June 30,		Change	% Change
	2020	2021		
Operating expenses:				
Research and development	\$ 329	\$ 942	\$ 613	186%
General and administrative	349	568	219	63%
Total operating expenses	<u>678</u>	<u>1,510</u>	<u>832</u>	<u>123%</u>
Loss from operations	(678)	(1,510)	(832)	123%
Other income (expenses):				
Interest expense	(4)	(573)	(569)	14,225%
Gain on extinguishment of debt	-	19	19	100%
Total other income (expenses)	<u>(4)</u>	<u>(554)</u>	<u>(550)</u>	<u>13,750%</u>
Net loss	<u>\$ (682)</u>	<u>\$ (2,064)</u>	<u>\$ (1,382)</u>	<u>203%</u>

Research and Development Expenses

Research and development expenses increased by approximately \$613,000, or 186%, from the six months ended June 30, 2020 to the six months ended June 30, 2021. The increase in research and development expenses was primarily due to an increase in stock compensation expense of \$394,000. In addition, development costs increased \$219,000 due to product formulation and consulting services in the current period.

General and Administrative Expenses

General and administrative expenses increased by \$219,000, or 63%, from the six months ended June 30, 2020 to the six months ended June 30, 2021 primarily due to an increase in accounting and professional services costs of \$190,000. In addition, labor costs increased \$30,000 and stock compensation costs increased \$11,000. These increases were partially offset by a \$12,000 decrease in travel expenses.

Other Income (Expenses)

Other income (expenses) increased by \$550,000, or 13,750% from the six months ended June 30, 2020 to the six months ended June 30, 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 the forgiveness of our Paycheck Protection Program loan of \$19,000.

Liquidity and Capital Resources

Sources of Liquidity

Since our formation through June 30, 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 six months ended June 30, 2021, we raised \$1,098,000 through the issuance of convertible notes to investors. We had nominal cash of \$1,000 on hand as of June 30, 2021.

As a result of our initial public offering (“IPO”), on July 13, 2021 we began trading on the Nasdaq Capital Market under the symbol “UNCY”, and on July 15, 2021 we received approximately \$23,212,000 in net proceeds after deducting the underwriting discounts and commissions and estimated offering expenses. We intend to use the net proceeds from the IPO to complete pre-clinical and clinical studies, submit regulatory filings to the FDA, and for general and corporate purposes, including hiring additional management and conducting market research and other commercial planning.

Future Funding Requirements

We have incurred net losses since our inception. For the six months ended June 30, 2021, we had a net loss of \$2.1 million, and we expect to incur substantial additional losses in future periods. As of June 30, 2021, we had an accumulated deficit of \$8.0 million.

We expect to continue incurring losses for the foreseeable future and will be required to raise additional capital in the future to complete our clinical trials, pursue product development initiatives and penetrate markets for the sale of our products. We believe that we will continue to have access to capital resources through possible equity offerings, debt financings, corporate collaborations or other means. There can be no assurance that we will be able to obtain additional financing on terms acceptable to us, on a timely basis or at all. If we are unable to secure additional capital, we may be required to curtail any clinical trials and development of new or existing products and take additional measures to reduce expenses in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. Based on the Company’s current level of expenditures, given the Company’s nominal cash balance of \$1,000 as of June 30, 2021, and after including the net proceeds received on July 15, 2021 as a result of the Company’s IPO, the Company believes that it has sufficient resources to continue operations for at least one year after the date that these financial statements are to be issued.

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

- the scope, timing, rate of progress and costs of our drug discovery efforts, pre-clinical development activities, laboratory testing and clinical trials for our current product candidates and future product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our current product candidates and future product candidates;

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

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

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

Related Party Payable

We entered into a Service Agreement on July 1, 2017, as amended on April 6, 2020 (“Service Agreement”), with Globavir Biosciences, Inc. (“Globavir”). Our Chief Executive Officer is also the Chief Executive Officer of Globavir. Pursuant to the Service Agreement, we receive administrative, consulting services, shared office space and other services in connection with 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 June 30, 2021, and December 31, 2020, respectively, \$38,000 was prepaid to and \$9,000 was payable to Globavir for service fees. Service fee expenses were \$30,000 and \$30,000 for the six months ended June 30, 2021 and 2020, respectively, and were recorded as expense in general and administrative expenses in the statements of operations.

Convertible Notes

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

We accounted for the 2021 Notes as stock-settled debt and we are accreting the carrying amount of the 2021 Notes to the settlement amount through maturity. As of June 30, 2021, unpaid and accrued interest of \$49,000 as well as debt discount accretion expense of approximately \$172,000 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 June 30, 2021, unpaid and accrued interest of \$130,000 as well as debt discount accretion expense of approximately \$460,000 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 \$573,000 and \$4,000 for the six months ended June 30, 2021 and 2020, respectively. Accrued interest of \$179,000 was included with the principal amount on the balance sheet within convertible notes as of June 30, 2021.

Summary of Cash Flows

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

	Six Months Ended	
	June 30,	
	2020	2021
	(unaudited)	(unaudited)
Net cash (used in) provided by:		
Operating activities	\$ (215)	\$ (890)
Financing activities	201	891
Net (decrease) increase in cash	\$ (14)	\$ 1

Cash Flows from Operating Activities

Net cash used in operating activities was \$0.9 million for the six months ended June 30, 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 \$2.1 million.

Net cash used in operating activities was \$0.2 million for the six months ended June 30, 2020. Cash used in operating activities resulted from a net loss of \$0.7 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 \$0.1 million.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$0.9 million for the six months ended June 30, 2021 and was primarily related to the issuance of convertible notes to investors for \$1.1 million as well as the receipt of \$0.1 million in proceeds from the exercise of options. Net repayments on loans from our chief executive officer offset the cash inflows by \$0.2 million.

Net cash provided by financing activities was \$0.2 million for the six months ended June 30, 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 June 30, 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.

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 quarterly report 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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

As of the end of the period covered by this Quarterly Report on Form 10-Q, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon this evaluation, the Chief Executive Officer and Chief Financial Officer each concluded that the Company's disclosure controls and procedures were not effective to provide reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and forms, and that such information has been accumulated and communicated to the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, in a manner that allows timely decisions regarding required disclosure.

In evaluating the effectiveness of our internal control over financial reporting, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework 2013. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer determined, based upon the existence of the material weakness described below, that we did not maintain effective internal control over financial reporting as of June 30, 2021.

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

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

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

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

- Increased the number of accounting personnel;
- Begin discussions with third party experts to assist management in completing a comprehensive risk assessment to identify, design and implement control activities; and
- Begin reviewing and enhancing business policies, procedures and related internal controls to standardize business processes.

We expect to complete the remediation by the end of 2021. We expect to incur additional costs to remediate this weakness, primarily personnel costs.

Changes in Internal Control Over Financial Reporting

There have been no changes in the Company's internal control over financial reporting identified in connection with the evaluation that occurred during the second quarter ended in 2021 that have materially affected, or are reasonably likely to materially affect, the internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The Company is not currently a party to any material legal proceedings and is not aware of any pending or threatened legal proceeding against the Company that the Company believes could have a material adverse effect on its business, operating results, cash flows or financial condition. The Company may periodically be the subject of various pending or threatened legal actions and claims arising out of its operations in the normal course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on the Company because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained. In the opinion of management of the Company, adequate provision has been made in the Company's financial statements at June 30, 2021 with respect to such matters.

ITEM 1A. 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 quarterly report and previously filed registration statement on Form S-1, 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 six months ended June 30, 2020 and 2021 was \$0.7 million and \$2.1 million, respectively, and our accumulated deficit as of June 30, 2021 was \$8.0 million. There can be no assurance that the product candidates currently under development or that may be under development by us in the future will be approved for sale in the U.S. or elsewhere. Furthermore, there can be no assurance that if such products are approved they will be successfully commercialized, and the extent of our future losses and the timing of our profitability are highly uncertain. If we are unable to achieve profitability, we may be unable to continue our operations.

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

We will need to continue to seek capital from time to time to continue development of our product candidates. We expect the net proceeds of our initial public offering, which was completed on July 15, 2021, will be sufficient to satisfy our capital requirements for a period of at least 12 months from the date the financial statements are to be issued. 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 equity offerings and debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, or through the issuance of shares under management or other types of contracts, or upon the exercise or conversion of outstanding derivative securities, the ownership interests of our stockholders will be diluted, and the terms of such financings may include liquidation or other preferences, anti-dilution rights, conversion and exercise price adjustments and other provisions that adversely affect the rights of our stockholders, including rights, preferences and privileges that are senior to those of our holders of common stock in the event of a liquidation. In addition, debt financing, if available, could include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures, entering into licensing arrangements, or declaring dividends and may require us to grant security interests in our assets. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, product or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may need to curtail or cease our operations.

Risks Related to Our Business

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

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

- the FDA may disagree with the design or implementation of our clinical trials;

- the FDA could determine that we cannot rely on Section 505(b)(2) for our current or future product candidates; and
- the FDA may determine that we have identified the wrong reference listed drug or drugs or that approval of our Section 505(b)(2) application for any of our product candidates is blocked by patent or non-patent exclusivity of the reference listed drug or drugs.

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

Obtaining clearances or approvals from the FDA and from the regulatory agencies in other countries is an expensive and time-consuming process and is uncertain as to outcome. The FDA and other agencies could ask us to supplement our submissions, collect non-clinical data, conduct additional clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain an NDA approval or pre-market approvals in other countries, the approval could be revoked or other restrictions imposed if post-market data demonstrate safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA will act. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be adversely affected, and our ability to grow domestically and internationally may be limited. Additionally, even if cleared or approved, our products may not be approved for the specific indications that are most necessary or desirable for successful commercialization or profitability.

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

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

- delays in reaching, or failing to reach, a consensus with regulatory agencies on study design;
- delays in reaching, or failing to reach, agreement on acceptable terms with a sufficient number of prospective contract research organizations (“CROs”) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in recruiting a sufficient number of suitable patients to participate in our clinical studies;
- imposition of a clinical hold by regulatory agencies, after an inspection of our clinical study operations or study sites;
- failure by our CROs, other third parties or us to adhere to clinical study, regulatory or legal requirements;
- failure to perform in accordance with the FDA's good clinical practices (“GCPs”) or applicable regulatory guidelines in other countries;

- delays in the testing, validation, manufacturing and delivery of sufficient quantities of our product candidates to the clinical sites;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- clinical study sites or patients dropping out of a study;
- delay or failure to address any patient safety concerns that arise during the course of a trial;
- unanticipated costs or increases in costs of clinical trials of our product candidates;
- occurrence of serious adverse events associated with the product candidates that are viewed to outweigh its potential benefits; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the Institutional Review Board (“IRB”) or Ethics Commission (“EC”) of the institutions in which such trials are being conducted, by an independent Safety Review Board (“SRB”) for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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

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

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

- be delayed in obtaining marketing approval for our product candidates, if approved at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be required to change the way the product is administered;
- be required to perform additional clinical studies to support approval or be subject to additional post-marketing testing requirements;

- have regulatory authorities withdraw their approval of a product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- be sued; or
- experience damage to our reputation.

Additionally, our product candidates could potentially cause other adverse events that have not yet been predicted. The inclusion of ill patients in our clinical studies may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using. As described above, any of these events could prevent us from achieving or maintaining market acceptance of our product candidates and impair our ability to commercialize our products.

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

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

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

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

Modifications to our products may require new NDA approvals.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the United States, new and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product-licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial marketing approval is granted. As a result, we might obtain marketing approval for a drug in a particular country but then be subject to price regulations that delay its commercial launch, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to commercialize and generate revenue from our product candidates, even if our product candidates obtain marketing approval.

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

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

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

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

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

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

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial resources. As a result, we may forego or delay pursuit of opportunities with future product candidates or for other indications that later prove to have greater commercial potential than opportunities we pursue. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target markets for a particular product candidate or opportunity, we may relinquish valuable rights to that product candidate or opportunity through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or opportunity.

We may be adversely affected by the ongoing coronavirus pandemic.

The outbreak of the novel coronavirus COVID-19 (“COVID-19”) has evolved into a global pandemic. The coronavirus has spread to many regions of the world. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

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

Moreover, our clinical trials may be affected by the COVID-19 pandemic. Site initiation, participant recruitment and enrollment, participant dosing, availability and distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed due to changes in hospital or university policies, federal, state or local regulations, prioritization of hospital resources toward pandemic efforts, or other reasons related to the COVID-19 pandemic. If the coronavirus continues to spread, some participants and clinical investigators may not be able to execute clinical trial protocols per the expected timelines. The new mutations of the virus may also make it harder for us to predict the exact impact (if any) on the progression of COVID-19 on our development programs. For example, quarantines or other travel limitations (whether voluntary or required) may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if the spread of the COVID-19 pandemic continues and our operations are adversely impacted, we risk a delay, default and/or nonperformance under existing agreements which may increase our costs. These cost increases may not be fully recoverable or adequately covered by insurance.

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

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

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

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

We rely on suppliers, vendors and partners for certain key aspects of our business, including support for information technology systems and certain human resource functions. We do not control these partners, but we depend on them in ways that may be significant to us. If these parties fail to meet our expectations or fulfill their obligations to us, we may fail to receive the expected benefits. In addition, if any of these third parties fails to comply with applicable laws and regulations in the course of its performance of services for us, there is a risk that we may be held responsible for such violations as well. This risk is particularly serious in emerging markets, where corruption is often prevalent and where many of the third parties on which we rely do not have internal compliance resources comparable to our own. Any such failures by third parties, in emerging markets or elsewhere, could adversely affect our business, reputation, financial condition or results of operations.

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

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

Our reliance on third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other international regulatory authorities require us to comply with GCP standards for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, available at www.clinicaltrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

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

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

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

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party, including the inability to supply sufficient quantities or to meet quality standards or timelines; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with U.S. cGMPs or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with cGMPs or other applicable regulations, even if such failures do not relate specifically to our product candidates or approved products, could result in sanctions being imposed on us or the manufacturers, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of our product candidates and harm our business and results of operations.

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

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

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

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

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

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

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

- unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due to us under a collaboration;
- uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations;
- unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials;

- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities;
- initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or
- attempts by either party to terminate the agreement.

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

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

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

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

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

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

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

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

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

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

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

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

As of June 30, 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 Invents 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 manufacturers' 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 replace all or part of the ACA. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017 included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Congress may consider other legislation to repeal or replace elements of the ACA.

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Owning our Common Stock

The price of our common stock may fluctuate substantially.

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

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

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

Following our initial public offering, which was completed on July 15, 2021, our directors, executive officers and their respective affiliates beneficially own approximately 41% 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.

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 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 year ended December 31, 2020 and for the three and six month periods ended June 30, 2020 and 2021, we concluded that there were material weaknesses in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. While we are taking steps to remediate the material weaknesses in our internal control over financial reporting, we may not be successful in remediating such weaknesses which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. Furthermore, if we remediate our current material weaknesses but identify new material weaknesses in our internal control over financial reporting investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our core business.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

Exhibit No.	Description
31.1	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
104	Cover Page Interactive Data File - the cover page from the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 is formatted in Inline XBRL

+ Indicates a management contract or any compensatory plan, contract or arrangement.

Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on the 16th day of August, 2021.

Signature	Title	Date
<u>/s/ Shalabh Gupta</u> Shalabh Gupta	Chief Executive Officer, President and Chairman <i>(Principal Executive Officer)</i>	August 16, 2021
<u>/s/ John Townsend</u> John Townsend	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	August 16, 2021

CERTIFICATION

I, Shalabh Gupta, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Unicycive Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2021

/s/ Shalabh Gupta

Shalabh Gupta

Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION

I, John Townsend, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Unicycive Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2021

/s/ John Townsend

John Townsend
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATIONS PURSUANT TO
18 U.S.C. SECTION 1350,
AS ENACTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Unicycive Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Shalabh Gupta, Chief Executive Officer of the Company, certifies, pursuant to 18 U.S.C. § 1350, as enacted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 16, 2021

/s/ Shalabh Gupta

Shalabh Gupta
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATIONS PURSUANT TO
18 U.S.C. SECTION 1350,
AS ENACTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Unicycive Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), John Townsend, Chief Financial Officer of the Company, certifies, pursuant to 18 U.S.C. § 1350, as enacted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 16, 2021

/s/ John Townsend

John Townsend
Chief Financial Officer
(Principal Financial Officer)