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 March 31, 2023

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

4300 El Camino Real, Suite 210
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	□	Accelerated filer	□
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided 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 May 15, 2023, there were 15,233,836 shares of the Company's common stock, par value $0.001 per share, issued and outstanding.

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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, 2022	As of March 31, 2023 (Unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 455	$ 24,332
Prepaid expenses and other current assets	2,189	1,852
Total current assets	2,644	26,184
Right of use asset, net	152	997
Property, plant and equipment, net	22	21
Total assets	$ 2,818	$ 27,202
Liabilities, mezzanine equity, and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 892	$ 790
Accrued liabilities	2,237	1,698
Warrant liability	-	13,206
Operating lease liability - current	155	276
Total current liabilities	3,284	15,970
Operating lease liability – long term	-	715
Total liabilities	3,284	16,685
Commitments and contingencies (Note 8)		
Mezzanine equity:		
Series A-1 preferred stock, $0.001 par value per share–zero and 30,190 shares authorized at December 31, 2022 and March 31, 2023, respectively; zero and 30,190 shares issued and outstanding, liquidation preference of zero and $30.6 million at December 31, 2022, and March 31, 2023, respectively	-	25,599
Stockholders' deficit:		
Preferred stock, $0.001 par value per share – 10,000,000 and 9,969,810 shares authorized at December 31, 2022 and March 31, 2023, respectively; no shares issued and outstanding at December 31, 2022, and March 31, 2023	-	-
Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2022 and March 31, 2023; 15,231,655 shares issued and outstanding at December 31, 2022, and 15,233,836 shares issued and outstanding at March 31, 2023	15	15
Additional paid-in capital	33,516	33,475
Accumulated deficit	(33,997)	(48,572)
Total stockholders' deficit	(466)	(15,082)
Total liabilities, mezzanine equity, and stockholders' deficit	$ 2,818	$ 27,202

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 March 31,	
	2022	**2023**
Licensing revenues:	$ -	$ 675
Operating expenses:		
Research and development	1,933	3,030
General and administrative	1,604	1,847
Total operating expenses	3,537	4,877
Loss from operations	(3,537)	(4,202)
Other income (expenses):		
Interest income	-	14
Interest expense	-	(12)
Change in fair value of warrant liability	-	(10,375)
Total other income (expenses)	-	(10,373)
Net loss	$ (3,537)	$ (14,575)
Deemed dividend to Series A-1 preferred stockholders	-	(192)
Net loss attributable to common stockholders	$ (3,537)	$ (14,767)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.24)	$ (0.97)
Weighted-average shares outstanding used in computing net loss per share, basic and diluted	15,004,617	15,232,406

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.

Statements of Mezzanine Equity and Stockholders' Deficit
(In thousands, except share amounts)
(Unaudited)

	Series A-1 Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2021	-	$ -	14,996,534	$ 15	$ 32,408	$ (15,939)	$ 16,484
Net loss	-	-	-	-	-	(3,537)	(3,537)
Issuance of common stock for exercise of options	-	-	23,983	-	7	-	7
Stock-based compensation expense	-	-	-	-	290	-	290
Balance at March 31, 2022	-	$ -	15,020,517	$ 15	$ 32,705	$ (19,476)	$ 13,244

	Series A-1 Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficit
Balance at December 31, 2022	-	$ -	15,231,655	$ 15	$ 33,516	$ (33,997)	$ (466)
Net loss	-	-	-	-	-	(14,575)	(14,575)
Issuance of Series A-1 preferred stock, net of issuance costs and allocated fair value of warrant liability	30,190	25,407	-	-	-	-	-
Deemed dividends on Series A-1 preferred stock	-	192	-	-	(192)	-	(192)
Issuance of common stock for exercise of options	-	-	2,181	-	7	-	7
Stock-based compensation expense	-	-	-	-	144	-	144
Balance at March 31, 2023	30,190	$ 25,599	15,233,836	$ 15	$ 33,475	$ (48,572)	$ (15,082)

See accompanying notes to the financial statements

Unicycive Therapeutics, Inc.

Statements of Cash Flows
(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2022	**2023**
Cash flows from operating activities		
Net loss	$ (3,537)	$ (14,575)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	2	2
Stock-based compensation expense	290	144
Change in fair value of warrant liability	-	10,375
Amortization of operating lease right of use asset	37	43
Changes in assets and liabilities:		
Prepaid expense and other current assets	263	338
Accounts payable and accrued liabilities	24	(193)
Operating lease liability	(36)	(54)
Net cash used in operating activities	(2,957)	(3,920)
Cash flows from investing activities		
Purchases of property, plant, and equipment	(2)	-
Net cash used in investing activities	(2)	-
Cash flows from financing activities		
Payments on financed insurance policies	-	(240)
Issuance costs related to issuance of Series A-1 preferred stock and warrants	-	(2,153)
Proceeds from issuance of Series A-1 preferred stock and warrants	-	30,190
Net cash provided by financing activities	-	27,797
Net increase (decrease) in cash and cash equivalents	(2,959)	23,877
Cash and cash equivalents at the beginning of the period	16,579	455
Cash and cash equivalents at the end of the period	$ 13,620	$ 24,332
Supplemental cash flow information		
Accrued dividends on preferred stock	$ -	$ 192
Fair value of warrants issued in connection with the issuance of preferred stock	-	2,831
Deferred preclinical and other charges included in prepaid expenses and other current assets	275	121
Cash paid for income taxes	$ -	$ -

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. Future revenue streams may consist of collaboration or licensing revenue as well as product sales. The Company has generated approximately $0.7 million in licensing revenue during the three months ended March 31, 2023.

The Company has incurred operating losses and negative cash flows from operations since inception and expects to continue to incur negative cash flows from operations in the future. As the Company increases its research and development activities, the operating losses are expected to increase. The Company has historically relied on private equity offerings, debt financings and loans from a stockholder to fund its operations. As of December 31, 2022 and March 31, 2023, the Company had an accumulated deficit of $34.0 million and $48.6 million, respectively.

As a result of its initial public offering ("IPO"), on July 13, 2021 the Company began trading on the Nasdaq Capital Market under the symbol "UNCY", and on July 15, 2021 received approximately $22.3 million in net proceeds after deducting the underwriting discounts, commissions and other offering expenses. The Company has used the net proceeds from the IPO to complete pre-clinical and clinical studies, prepare regulatory filings for the FDA, and for general and corporate purposes, including hiring additional management and conducting market research and other commercial planning.

On March 3, 2023, the Company entered into a securities purchase agreement with certain healthcare-focused institutional investors that will provide up to $130.0 million in gross proceeds through a private placement and that includes initial upfront funding of $30.0 million.

The Company expects to continue incurring losses in the future and will be required to raise additional capital in the future to complete its planned clinical trials, pursue product development initiatives and penetrate markets for the sale of its products. Management believes that the Company will continue to have access to capital resources through possible equity offerings, debt financings, corporate collaborations or other means. In 2021, the Company received approximately $22.3 million in net proceeds from its IPO, and in March 2023 the Company received approximately $28.0 million in net proceeds from the sale of preferred stock. There can be no assurance that the Company will be able to obtain additional financing on terms acceptable to the Company, on a timely basis or at all. If the Company is unable to secure additional capital, it may be required to curtail any clinical trials and development of new or existing products and take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations. Based on the Company's current level of expenditures, and after receiving the proceeds from the private placement in March 2023, the Company believes that it has sufficient resources such that there is not substantial doubt about the ability to continue operations for at least one year after the date that these financial statements are available to be issued.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

The accompanying unaudited financial statements of the Company as of March 31, 2023 have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X and, accordingly, they do not include all information and footnote disclosures required by accounting principles generally accepted in the U.S. ("GAAP"). The Company believes the footnotes and other disclosures made in the financial statements are adequate for a fair presentation of the results of the interim periods presented. The financial statements include all adjustments (solely of a normal recurring nature) which are, in the opinion of management, necessary to make the information presented not misleading. You should read these financial statements and the accompanying notes in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the U.S. Securities and Exchange Commission ("SEC") on March 31, 2023.

Preferred Stock

The Company classifies its Series A-1 Preferred Stock (as defined in Note 10) outside of stockholders' deficit on the accompanying balance sheets as it is contingently redeemable upon the occurrence of an event that is not solely within the Company's control. The Company recorded the issuance of Series A-1 Preferred Stock at the residual value from proceeds after the allocation of the fair value of warrants, net of related and allocable issuance costs. As the Series A-1 Preferred Stock is not currently redeemable, and as the Company has determined that it is not probable of becoming redeemable, no subsequent remeasurement is required. Since the Company is obligated to pay cumulative dividends on the Series A-1 preferred stock whether or not declared by the Board of Directors, the Company accrues the dividends as they are earned, based on the stated contractual rate.

Warrant Liabilities

In conjunction with the issuance of Series A-1 Preferred Stock (see Note 10), the Company established a warrant liability as of March 3, 2023, representing the fair value of warrants that may be issued, subject to shareholder approval, upon conversion of the Series A-1 Preferred Stock. The Company accounts for these warrants as liabilities (in accordance with ASC 480) on the balance sheets as a result of certain redemption clauses that are not within the control of the Company. The warrant liabilities are initially measured at fair value, resulting in an implied discount on the related preferred stock financing arrangement (recognized as a partial offset to the carrying value of the Series A-1 Preferred Stock), and are remeasured at fair value each reporting period. Changes in the fair value of the warrant liabilities are recognized in earnings during each period. The warrant liabilities are measured using Level 3 fair value inputs. See Note 11 for a description of warrant liabilities and the related valuations.

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 revenues, stock-based compensation, research contract accruals and prepaid amounts, and the fair value of warrant liabilities. Actual results may materially differ from those estimates.

Segment Information

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

Risks and Uncertainties

The Company operates in a dynamic and highly competitive industry and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows: ability to obtain future financing; advances and trends in new technologies and industry standards; results of clinical trials; regulatory approval and market acceptance of the Company's products; development of sales channels; certain strategic relationships; litigation or claims against the Company related to intellectual property, product, regulatory, or other matters; and the Company's ability to attract and retain employees necessary to support its growth.

The Company's general business strategy may be adversely affected by any such economic downturns (including the current downturn related to the COVID-19 pandemic), volatile business environments and continued unstable or unpredictable economic and market conditions.

Any product candidates developed by the Company will require approvals from the FDA or other international regulatory agencies prior to commercial sales. There can be no assurance that the Company's current product candidates or any future product candidates will receive the necessary approvals. If the Company is denied approval, approval is delayed or the Company is unable to maintain approval, it could have a materially adverse impact on the Company.

The Company has expended and will continue to expend substantial funds to complete the research, development and clinical testing of its product candidates. The Company also will be required to expend additional funds to establish commercial-scale manufacturing arrangements and to provide for the marketing and distribution of products that receive regulatory approval. The Company will require additional funds to commercialize its products. The Company is unable to entirely fund these efforts with its current financial resources. If adequate funds are unavailable on a timely basis from operations or additional sources of financing, the Company may have to delay, reduce the scope of or eliminate one or more of its research or development programs, which would materially and adversely affect its business, financial condition and operations.

The Company is dependent upon the services of its employees, consultants and other third parties.

Property, Plant and Equipment

Property, plant, and equipment are recorded at cost less accumulated depreciation. Additions, improvements, and major renewals or replacements that substantially extend the useful life of an asset are capitalized. Repairs and maintenance expenditures are expensed as incurred. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, which range from three to seven years. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the remaining lease term.

Management assesses the carrying value of property and equipment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. If there is indication of impairment, management prepares an estimate of future cash flows expected to result from the use of the asset and its eventual disposition. If these cash flows are less than the carrying amount of the asset, an impairment loss is recognized to write down the asset to its estimated fair value at that time. At March 31, 2023, management determined there were no impairments of the Company's property and equipment.

Leases

The Company determines whether a contract is, or contains, a lease at inception. Right-of-use assets represent the Company's right to use an underlying asset during the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at lease commencement based upon the estimated present value of unpaid lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at lease commencement in determining the present value of unpaid lease payments.

Fair Value of Financial Instruments

The Company's financial instruments include warrants, cash and cash equivalents, prepaid expenses, and accounts payable.

Fair value is defined as the price that would be received for sale of an asset or paid for transfer of a liability, in an orderly transaction between market participants at the measurement date. U.S. GAAP establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The Company's warrants, recorded in the accompanying balance sheets, are categorized based on the inputs to valuation techniques as follows:

- Level 1 — defined as observable inputs based on unadjusted quoted prices for identical instruments in active markets;
- Level 2 — defined as inputs other than Level 1 that are either directly or indirectly observable in the marketplace for identical or similar instruments in markets that are not active; and
- Level 3 — defined as unobservable inputs in which little or no market data exists where valuations are derived from techniques in which one or more significant inputs are unobservable.

The fair value of the contingently issuable warrants associated with the Company's March 2023 private placement transaction, further described in Note 11 – Warrant Liability, were determined by using a Monte Carlo simulation technique ("MCS") to value the embedded derivatives associated with the warrants. The MCS methodology calculates the theoretical value of a warrant based on certain parameters, including: (i) the threshold of exercising the warrant, (ii) the price of the underlying security, (iii) the time to expiration, or expected term, (iv) the expected volatility of the underlying security, (v) the risk-free rate, (vi) the number of paths, and (vii) estimated probability assumptions surrounding shareholder approval as well as the achievement by the Company of technical milestones associated with regulatory and commercial progress. The Company estimated the probability of shareholder approval for the issuance of common shares upon the conversion of the Series A-1 Preferred Stock at 45% as of March 3, 2023 and March 31, 2023. The Company estimated probabilities of obtaining FDA approval for Renazorb, for acceptance into the proposed TDAPA program, and for achieving 4 quarters of commercial sales at 21%, 8%, and 5%, respectively, as of March 3, 2023 and March 31, 2023.

These valuation techniques involve management's estimates and judgment based on unobservable inputs and are classified in Level 3. The fair value estimates may not be indicative of the amounts that would be realized in a market exchange. Additionally, there may be inherent uncertainties or changes in the underlying assumptions used, which could significantly affect the current or future fair value estimates. Generally, a significant increase (decrease) in the probabilities of shareholder approval and the achievement of technical milestones would have resulted in a significantly higher (lower) fair value measurement; however, changes in other inputs such as expected term and price of the underlying common stock will have a directionally opposite impact on fair value measurement.

The following table summarizes the fair value hierarchy of financial liabilities measured at fair value as of March 31, 2023 (in thousands).

	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Warrant liability	$ -	$ -	$ 13,206	$ 13,206
Total liabilities at fair value	$ -	$ -	$ 13,206	$ 13,206

The following table summarizes the changes in fair value of the derivative liability classified in Level 3. Gains and losses reported in this table include changes in fair value that are attributable to unobservable inputs.

	Three Months Ended March 31, 2023
Fair value at January 1, 2023	$ -
Issuance of Warrants (March 3, 2023)	2,831
Change in fair value of Warrants	10,375
Fair value at March 31, 2023	$ 13,206

The expense relating to the change in fair value of the derivative liability of $10,375,000 for the three months ended March 31, 2023 is included in other income (expense) in the statements of operations.

ASC 820, Fair Value Measurement and Disclosures requires all entities to disclose the fair value of financial instruments, both assets and liabilities, for which it is practicable to estimate fair value. As of December 31, 2022 and March 31, 2023, the recorded values of cash and cash equivalents, prepaid expenses, and accounts payable approximated fair value due to the short-term nature of the instruments.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. All of the Company's cash was deposited in one account at a financial institution during 2022, and cash balances may at times exceed federally insured limits. For 2023 the Company's cash is distributed across multiple financial institutions. The cash and cash equivalents the Company uses to satisfy working capital and operating expense needs are currently held in accounts at various financial institutions. Cash and cash equivalents could be adversely impacted, including the loss of uninsured deposits and other uninsured financial assets, if one or more of the financial institutions in which the Company holds its cash or cash equivalents fails or is subject to other adverse conditions in the financial or credit markets.

Prepaid Expenses

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

Revenue Recognition

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

Research and Development Expenses

Substantially all of the Company's research and development expenses consist of expenses incurred in connection with the development of the Company's product candidates. These expenses include fees paid to third parties to conduct certain research and development activities on the Company's behalf, consulting costs, costs for laboratory supplies, product acquisition and license costs, certain payroll and personnel-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expenses for the Company's research and product development employees and allocated overheads, including information technology costs and utilities and expenses for issuance of shares pursuant to the anti-dilution clause in the purchase of IPR&D technology. The Company expenses both internal and external research and development expenses as they are incurred.

General and Administrative Expenses

General and administrative expenses represent personnel costs for employees involved in general corporate functions, including finance, accounting, legal and human resources, among others. Additional costs included in general and administrative expenses consist of professional fees for legal (including patent costs), audit and other consulting services, stock-based compensation and other general corporate overhead expenses as well as costs from a service agreement with a related party (See Note 7).

Patent Costs

The Company expenses all costs as incurred in connection with patent licenses and applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are reflected in general and administrative expenses in the statements of operations.

Stock-Based Compensation

The Company accounts for stock-based compensation for all share-based payments made to employees and non-employees by estimating the fair value on the date of grant and recognizing compensation expense over the requisite service period on a straight-line basis. The Company recognizes forfeitures related to stock-based compensation as they occur. The Company estimates the fair value of stock options using the Black-Scholes option-pricing model. The Black-Scholes model requires the input of subjective assumptions, including expected common stock volatility, expected dividend yield, expected term, risk-free interest rate, and the estimated fair value (prior to the Company's initial public offering) or the public market closing price of the Company's underlying common stock on the date of grant.

Income Taxes

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

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

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

Comprehensive Loss

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

Net Loss per Share

Basic and diluted net loss per share is presented in conformity with the two-class method required for participating securities. Basic and diluted net loss for common stock and for preferred stock is computed by dividing the sum of distributed earnings and undistributed earnings for each class of stock by the weighted average number of shares outstanding for each class of stock for the period. Diluted net loss per share includes potentially dilutive securities outstanding for the period. As the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

Recent Accounting Pronouncements

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

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

3. Significant Agreements

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

In October 2017, the Company entered into an exclusive license agreement with Sphaera, a stockholder, for the rights to further develop the drug candidate, UNI 494, for commercialization. No payments were made upon execution of the agreement but rather payments for $50,000 will be due commencing with the initiation by the Company of a second clinical trial and $50,000 on completion of such trial. At the time the FDA accepts a NDA application submitted by the Company for the product, the Company will pay Sphaera $1.65 million. Upon commercialization and sale of the drug product, royalty payments will also be payable quarterly to Sphaera equal to 2% of net sales on the preceding quarter.

In September 2018, the Company entered into an Assignment and Asset Purchase Agreement with Spectrum Pharmaceuticals, Inc. ("Spectrum Agreement") pursuant to which the Company purchased certain assets from Spectrum, including Spectrum's right, title, interest in and intellectual property related to Renazorb RZB 012, also known as RENALAN™ ("Renalan") and RZB 014, also known as SPI 014 ("SPI" and together with Renalan, the "Compounds"), to further develop and commercialize Renazorb and related compounds. In partial consideration for the Spectrum Agreement, the Company issued 313,663 shares of common stock to Spectrum valued at approximately $4,000 which represented four percent of the Company on a fully-diluted basis at the date of the execution of the Spectrum Agreement. The Spectrum Agreement has an anti-dilution provision, which provides that Spectrum maintain its ownership interest in the Company at 4% of the Company's shares on a fully-diluted basis. Fully-diluted shares of common stock for purposes of the Renazorb Purchase Agreement assumes conversion of any security convertible into or exchangeable or exercisable for common stock or any combination thereof, including any common stock reserved for issuance under a stock option plan, restricted stock plan, or other equity incentive plan approved by the Board of Directors of the Company immediately following the issuance of additional shares of the Company's common stock (but prior to the issuance of any additional shares of common stock to Spectrum). Spectrum's ownership shall not be subject to dilution until the earlier of thirty-six months from the first date the Company's stock trades on a public market, or the date upon which the Company attains a public market capitalization of at least $50 million. On July 13, 2021, the Company's initial public offering resulted in a public market capitalization of at least $50 million, and as a result the Company was required to issue 438,374 anti-dilution shares of common stock. This issuance represented the final anti-dilution calculation required under the Spectrum Agreement, and no further anti-dilution shares will be issued. The Company calculated the fair value of the shares and recognized $2.2 million to research and development expenses as cost to issue those shares during the third quarter of 2021. In the event an NDA filing for Renazorb is accepted by the FDA, the Company will be required to pay $0.2 million to Altair Nanomaterials, Inc., ("Altair") in accordance with the Spectrum Agreement. In addition, in the event FDA approval for Renazorb is received, the Company will be required to pay $4.5 million to Altair. The Company is also required to pay Spectrum 40% of all of the Company's sublicense income for any sublicense granted to certain sublicensees during the first 12 months after the Closing Date (as that term is defined in the Renazorb Purchase Agreement) and 20% of all other sublicense income. The Company's payment obligations to Spectrum will expire on the twentieth (20^{th}) anniversary of the Closing Date of the Renazorb Purchase Agreement. In August 2022, the Company received an upfront payment of approximately $1.0 million as a result of a sublicense development agreement with Lee's Pharmaceutical (HK) Limited. The payment represents sublicense income as described in the Spectrum Agreement, and 20% of the amount received has been accrued as an R&D expense in the accompanying statements of operations for the year ended December 31, 2022. In February 2023, the Company received an upfront payment of approximately $0.7 million as a result of a sublicense development agreement with Lotus International Pte Ltd. The payment represents sublicense income as described in the Spectrum Agreement, and 20% of the amount received has been accrued as an R&D expense in the accompanying statements of operations for the three months ended March 31, 2023.

On July 19, 2021, the Company entered into an agreement with Syneos Health LLC ("Syneos") pursuant to which Syneos will provide preclinical research and analysis services related to the development of UNI-494. The initial budget for the study, which includes clinical pharmacology, translational sciences, and bioanalytical services, was approximately $2.3 million. Related payments totaling approximately $2.0 million have been paid to Syneos as of March 31, 2023.

On January 6, 2022, the Company entered into a Master Services Agreement with Quotient Sciences Limited ("Quotient"), a UK based company that provides drug development and analysis services, for the purpose of performing clinical research in support of UNI-494. The initial budget for the study is approximately $3.7 million, and subsequent revisions reduced the overall budget to $2.6 million. Related payments totaling approximately $1.9 million have been paid to Quotient as of March 31, 2023, approximately $0.9 million of related expense has been recorded, and approximately $1.0 million has been recorded as prepaid expense in the accompanying balance sheet as of March 31, 2023.

On February 9, 2022, the Company entered into a Master Services Agreement with CBCC Global Research Inc. ("CBCC"), a California based company that provides clinical trial and related services, for the purpose of performing clinical research in support of Renazorb. The budget for the initial study was approximately $1.4 million. Payments relating to the initial agreement totaling approximately $0.4 million have been paid to CBCC as of March 31, 2023, and approximately $0.4 million of related expense has been recorded. In September 2022, a statement of work revised the remaining services budget to approximately $0.1 million.

On June 29, 2022, the Company entered into an Agreement with Inotiv, an Indiana based company that provides preclinical trial and related services, for the purpose of performing research in support of Renazorb. The budget for the services is approximately $1.0 million. Approximately $0.8 million has been paid to Inotiv as of March 31, 2023 and approximately $0.1 million has been recorded as prepaid expense in the accompanying balance sheet as of March 31, 2023.

On July 14, 2022, the Company entered into a license agreement with Lee's Pharmaceutical (HK) Limited (see Note 4). Under the terms of the agreement, Lee's Pharmaceutical will be responsible for development, registration filing and approval for Renazorb in China, Hong Kong, and certain other Asian markets. In addition, Lee's Pharmaceutical will have sole responsibility for the importation of the drug product from the Company and for the costs of commercialization of Renazorb in the licensed territories. The Company has received an upfront payment of $1.0 million, expects to receive up to $1.0 million in milestone payments upon product launch in China and will be eligible for tiered royalties of between 7% and 10% upon achievement of prespecified regulatory and commercial achievements.

On July 27, 2022, the Company entered into an Agreement with Celerion, a Nebraska based company that provides clinical trial and related services, for the purpose of performing research in support of Renazorb. The budget for the services is approximately $2.7 million, and approximately $2.7 million has been paid to Celerion as of March 31, 2023.

On February 1, 2023, the Company entered into a license agreement with Lotus International Pte Ltd. ("Lotus") (see Note 4). Under the terms of the agreement, Lotus will be responsible for development, registration filing and approval for Renazorb in the licensed territory of South Korea. In addition, Lotus will have sole responsibility for the importation of the drug product from the Company and for the costs of commercialization of Renazorb in the licensed territory. The Company has received an upfront payment of $0.7 million, may receive up to $3.7 million in future milestone payments and will be eligible for tiered royalties upon achievement of specified commercial achievements.

4. Licensing Revenues

On July 14, 2022, the Company entered into a license agreement ("Agreement") with Lee's Pharmaceutical (HK) Limited ("Lee's"). Under the terms of the agreement, Lee's Pharmaceutical will be responsible for development, registration filing and approval for Renazorb in China, Hong Kong, and certain other Asian markets. In addition, Lee's will have sole responsibility for the importation of the drug product from the Company and for the costs of commercialization of Renazorb in the licensed territories. Both parties agreed to enter into a separate manufacturing and supply agreement whereby Unicycive will supply Lee's with Renazorb product. The Company has received an upfront payment of approximately $1.0 million, expects to receive up to $1.0 million in milestone payments upon product launch in China and will be eligible for tiered royalties of between 7% and 10% upon achievement of prespecified regulatory and commercial achievements.

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

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

ASC 606 indicates that constrained variable consideration should be included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration consisting of milestone payments and sales-based royalties may be received based on the completion of certain clinical, regulatory, and commercial activities. The Company has concluded that the future milestone payments should be excluded from the transaction price due to the uncertainty of achievement as of March 31, 2023. The Company will reassess this conclusion at each reporting date until the uncertainties are resolved.

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

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

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

On February 1, 2023, the Company entered into a license agreement with Lotus International Pte Ltd. ("Lotus"). Under the terms of the agreement, Lotus will be responsible for development, registration filing and approval for Renazorb in the licensed territory of South Korea. In addition, Lotus will have sole responsibility for the importation of the drug product from the Company and for the costs of commercialization of Renazorb in the licensed territory. The Company has agreed to complete development of the drug product, at its own expense, as required for obtaining regulatory approval in the U.S. Both parties agreed to enter into a separate manufacturing and supply agreement whereby Unicycive will supply Lotus with Renazorb product. The Company has received an upfront payment of $0.7 million, may receive up to $3.7 million in future milestone payments and will be eligible for tiered royalties upon achievement of specified commercial achievements.

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

The Company does not believe that its promise to provide goods under a future manufacturing and supply agreement represents a material right to Lotus, and therefore the promise does not represent a current performance obligation. The Company evaluated the development services and concluded that although not material in cost, they are highly interrelated with the license grant. If a promised good or service is not distinct, an entity is required to combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct. The combination of the license grant and development services is distinct as Lotus plans to use the product of this bundled unit for developing its regulatory applications. The Company concluded that the Lotus agreement contains one performance obligation, the bundle of the license grant and development services.

ASC 606 indicates that constrained variable consideration should be included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration consisting of milestone payments and sales-based royalties may be received based on the completion of certain clinical, regulatory, and commercial activities. The Company has concluded that the future milestone payments should be excluded from the transaction price due to the uncertainty of achievement as of March 31, 2023. The Company will reassess this conclusion at each reporting date until the uncertainties are resolved.

For the sales-based royalty payments, guidance requires an entity to recognize revenue for a sales-based royalty promised in exchange for a license of intellectual property only when the later of 1) the subsequent sale or usage occurs, or 2) the performance obligation to which some or all the sales-based or usage-based royalty has been allocated has been satisfied or partially satisfied. The Company has concluded that the future sales-based royalties should be excluded from the transaction price as of March 31, 2023. The Company will reassess this conclusion at each reporting date.

The Company has concluded that at contract inception the total transaction price is the $675,000 amount of the upfront payment. ASC 606 generally requires an entity to allocate the transaction price to the performance obligations in proportion to their standalone selling prices (i.e., on a relative standalone selling price basis). The Company identified the bundle of the license grant and development services as the single performance obligation in the agreement. The $675,000 initial transaction price will therefore be entirely allocated to this obligation.

The Company has concluded that the license of the Renazorb IP is functional IP. However, since it is not distinct, revenue must be recognized based on the combination of the functional IP and the related development services. Lotus will not simultaneously receive and consume the benefits of the Renazorb IP or development services. Since the performance of the development services creates an asset that will also be used by the Company and can be licensed to other customers outside of the Territory, the Company is considered to control the asset as it is created and it does create an asset with an alternative use. Therefore the Company concluded that control is not deemed to be transferred over time and is instead transferred at a point in time. The intellectual property was transferred to Lotus in February 2023, and the development services were determined to be immaterial to the contract. The Company has recognized a total of $675,000 in the accompanying statements of operations as licensing revenue for the three months ended year ended March 31, 2023.

5. Balance Sheet Components

Prepaid expenses and other current assets as of December 31, 2022 and March 31, 2023 consisted of the following (in thousands):

	As of December 31, 2022	As of March 31, 2023
Prepaid directors and officers' liability insurance premiums	$ 476	$ 337
Prepaid preclinical services	1,554	1,196
Other	159	319
Total	$ 2,189	$ 1,852

Property, plant and equipment as of December 31, 2022 and March 31, 2023 consisted of the following (in thousands):

	As of December 31, 2022	As of March 31, 2023
Leasehold improvements	$ 15	$ 15
Furniture and fixtures	14	14
Subtotal	29	29
Less accumulated depreciation	(7)	(8)
Net	$ 22	$ 21

Accounts payable as of December 31, 2022 and March 31, 2023 consisted of the following (in thousands):

	As of December 31, 2022	As of March 31, 2023
Trade accounts payable	$ 846	$ 610
Credit card liability	46	180
Total	$ 892	$ 790

Accrued liabilities as of December 31, 2022 and March 31, 2023 consisted of the following (in thousands):

	As of December 31, 2022	As of March 31, 2023
Accrued labor costs	$ 1,487	$ 610
Accrued drug development costs	228	766
Other	522	322
Total	$ 2,237	$ 1,698

6. Operating Lease

The Company leases office space under an operating lease. In December 2021, the Company entered into a lease agreement for 2,367 square feet of office space commencing December 1, 2021. The initial lease term was for two years, and there was an option to extend the lease for an additional year. On March 3, 2023, the Company expanded its leased space through a lease amendment by an additional 2,456 square feet commencing March 15, 2023. The term of the amended lease is for three years with an option to extend the lease for three additional years.

In accounting for the leases, the Company adopted ASC 842 Leases on January 1, 2019, which requires a lessee to record a right-of-use asset and a corresponding lease liability at the inception of the lease initially measured at the present value of the lease payments. The lease amendment represents a modification of the original lease, and the Company evaluated the new agreement under ASC 842. The Company classified the lease as an operating lease and, at March 15, 2023, determined that the present value of the lease was approximately $1.0 million using a discount rate of 10.0%. In accordance with ASC 842, the right-of-use asset will be amortized over the life of the underlying lease. The Company determined that the option to extend the lease for an additional three years was not considered reasonably certain at March 31, 2023. During the three months ended March 31, 2023, the Company reflected amortization of right-of-use asset of approximately $44,000, resulting in a right of use asset balance of approximately $1.0 million.

During the three months ended March 31, 2023, the Company made cash payments on the lease of $65,000 towards the lease liabilities. As of March 31, 2023, the total lease liability was approximately $1.0 million. ASC 842 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. Rent expense for the lease for the three months ended March 31, 2023 was $54,000.

As of March 31, 2023, maturities of the Company's lease liabilities are as follows (in thousands, unaudited):

	Operating Lease
Year ending December 31, 2023	$ 266
Year ending December 31, 2024	391
Year ending December 31, 2025	424
Year ending December 31, 2026	72
Total lease payments	1,153
Less imputed interest rate / present value discount	(162)
Present value of lease liability	991
Less current portion	(276)
Long term portion	$ 715

7. Related Party Transactions

Loan from Chief Executive Officer and Stockholder

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

Common Stock Purchase Agreement and Service Agreement with Globavir

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

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

8. Commitments and Contingencies

Contingencies

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

Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications, including for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but that have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations.

The Company believes that the likelihood of conditions arising that would trigger these indemnities is remote and, historically, the Company had not made any significant payment under such indemnification provisions. Accordingly, the Company has not recorded any liabilities relating to these agreements. However, the Company may record charges in the future as a result of these indemnification obligations.

Additionally, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at the Company's request in such capacity. The indemnification period covers all pertinent events and occurrences during the director's or officer's service.

Employee Benefit Plan

In December 2021, the Company implemented a 401(k) Plan which covers all eligible employees of the Company (the "401(k) Plan"). Employer matching contributions are immediately 100% vested. The Company's 401(k) Plan provides that the Company match each participant's contribution at 100% up to 4% of the employee's eligible compensation. Company contributions to the 401(k) Plan totaled approximately $60,000 and $21,000 for the year ended December 31, 2022 and for the three months ended March 31, 2023, respectively.

9. 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 and Warrants from Initial Public Offering

During July 2021, as a result of its initial public offering, the Company issued 5,000,000 shares of common stock and 4,000,000 warrants to investors in exchange for cash at $5.00 per unit, consisting of $4.99 per share of common stock and $.0125 per four fifths of a warrant. The warrants have a 5-year term and an exercise price of $6.00 per warrant. The underwriters exercised their option to purchase an additional 600,000 warrants, and the Company received $7,500 in proceeds.

As a result of the initial public offering, the Company's outstanding convertible notes and unpaid accrued interest were converted into 736,773 shares of common stock. Additionally, in accordance with the original terms of the warrant agreements convertible noteholders were granted a total of 184,193 common stock warrants with a 5-year term and with an exercise price of $6.00 per warrant.

The following table summarizes activity for the Company's common stock warrants for the three months ended March 31, 2023:

	Number of Shares Underlying Outstanding Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2022	4,784,193	6.00	3.54	-
Warrants granted	-	-	-	-
Warrants exercised	-	-	-	-
Outstanding, March 31, 2023	4,784,193	6.00	3.29	-

See Note 11 for information on contingently issuable preferred stock warrants associated with our sale in March of Series A-1 Preferred Stock.

Voting Rights of Common Stock

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

Note 10. Issuance of Series A-1 Preferred Stock

As of December 31, 2022, the Company had 10,000,000 shares of preferred stock authorized, par value of $0.001 per share, and no shares of preferred stock were issued or outstanding. As of March 31, 2023, as a result of the Company's private placement financing, there were 30,190 shares of Series A-1 Preferred Stock issued and outstanding.

On March 3, 2023, the Company issued and sold, in a private placement, 30,190 shares of Series A-1 Preferred Stock for an aggregate net proceeds of $28.0 million (the "Preferred Stock Offering"), net of placement agent fees and offering expenses of $2.2 million. The Company intends to use the net proceeds from the Preferred Stock Offering to support the Company's New Drug Application (NDA) submission for approval of Renazorb for the treatment of hyperphosphatemia and, if approved, for the commercial launch of Renazorb in the U.S.

Pursuant to the Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock (the "Certificate of Designation"), each share of Series A-1 Preferred Stock is, subject to approval of the Company's stockholders, convertible into a unit ("Unit") consisting of: (i) shares of common stock of the Company and, if applicable, shares of Series A-2 Preferred Stock, in lieu of Common Stock, (ii) a tranche A warrant to acquire approximately 46,675,940 shares of Series A-3 Preferred Stock (the "Tranche A Warrant"), (iii) a tranche B warrant to acquire approximately 42,432,672 shares of Series A-4 Preferred Stock (the "Tranche B Warrant"), and (iv) a tranche C warrant to acquire approximately 67,892,276 shares of Series A-5 Preferred Stock (the "Tranche C Warrant", together with the Tranche A Warrant and the Tranche B Warrant, the "Warrants"). The Tranche A warrants for an aggregate exercise price of approximately $25 million are exercisable until 21 days following the Company's announcement of receipt of FDA approval for Renazorb, the Tranche B warrants for an aggregate exercise price of approximately $25 million are exercisable until 21 days following the Company's announcement of receipt of Transitional Drug Add-On Payment Adjustment ("TDAPA") approval for Renazorb, and the Tranche C Warrant for an aggregate exercise price of approximately $50 million are exercisable until 21 days following four quarters of commercial sales of Renazorb following receipt of TDAPA approval.

The Company has designated 30,190 shares of Series A-1 Preferred Stock, 1,800,000 shares of Series A-2 Preferred Stock, 1,800,000 shares of Series A-3 Preferred Stock, 1,800,000 shares of Series A-4 Preferred Stock, and 3,600,000 shares of Series A-5 Preferred Stock, together the "Series A Preferred Stock". The Series A Preferred Stock has a par value of $0.001 per share. The Certificate of Designation states that, to the extent that the conversion of the Series A-1 preferred stock as well as the exercise of the Tranche A, B, and C warrants into Series A-2, Series A-3, Series A-4, and Series A-5 preferred stock results in a beneficial ownership interest in excess of the maximum percentage of common stock upon conversion, the holders will receive the as converted equivalent for the remaining shares in preferred stock on a one-for-one basis with common shares. As the Company does not currently have sufficient authorized shares of preferred stock available to satisfy the one-for-one conversion to Series A preferred stock, the Company may be required to seek shareholder approval for an increase in the number of authorized preferred shares. However, it is the Company's intent to modify the language of the Certificate of Designation such that the conversion will reflect a $1,000 per share value for the preferred stock expected to be issued as Series A-2, Series A-3, Series A-4, and Series A-5 preferred stock.

The Company determined that the holders can detach the warrants from the Series A-1 preferred stock, because the stock will automatically convert into shares of common stock, and the holders will be able to sell those shares while retaining the warrants. Accordingly, the warrants are considered freestanding from the Series A-1 preferred stock. The Company noted that at contract inception, the warrants are contingently issuable upon the occurrence of a specified event (shareholder approval). Once the warrants are legally issued as a result of the automatic conversion of the Series A-1 preferred stock upon shareholder approval, they will become immediately exercisable at the option of the holder. The Company determined that the contingently issuable warrants qualify as derivative instruments pursuant to ASC 815-40 and that the warrants will be considered issued for accounting purposes concurrently with the Series A-1 Preferred Stock.

In connection with the Series A-1 Preferred Stock issuance, the Company recognized liabilities for the associated Warrants, which had an aggregate fair value of $2.8 million at the time of issuance. $0.2 million of offering costs were allocated to the Warrants and expensed during the three months ended March 31, 2023. The fair value of the Warrants were accounted for as a reduction to the net proceeds of the Preferred Stock Offering, which resulted in an initial carrying value of $25.4 million for the Series A-1 Preferred Stock (net of $2.0 million of placement agent fees and offering costs allocated to the Series A-1 Preferred Stock). Refer to Note 11 for disclosures related to the Warrants.

The Series A-1 Preferred Stock have the following rights:

Dividends: Prior to the receiving stockholder approval, dividends will accrue, on all issued and outstanding shares of Series A-1 Preferred Stock, prior to and in preference to all other shares of capital stock of the Company, at an annual rate of eight percent (8%) compounded annually on the original per share price (plus any such accreted compounded amounts); provided that such annual dividend rate shall increase to fourteen percent (14%) if stockholder approval is not obtained at the first meeting of stockholders following the date of the Preferred Stock offering. If such dividends are not declared and paid in cash, the dividend amounts will be added to the aggregate liquidation preference then outstanding of the Series A-1 Preferred Stock. As of March 31, 2023, the Company has recorded $0.2 million, or $6.36 per share, of deemed dividends on the outstanding Series A-1 Preferred Stock.

Voting: Holders of the Series A-1 Preferred Stock are entitled to vote together with the common stock on an as-if-converted-to-common-stock basis as determined by dividing the liquidation preference with respect to such shares of Series A Preferred Stock by the conversion price. Holders of common stock are entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders.

Board of Directors Designation Rights: The holders of Series A-1 Preferred Stock have the right to appoint one member to the Board of Directors.

Conversion: Prior to the receipt of stockholder approval, the Series A-1 Preferred Stock is not convertible by the holder thereof. The Company intends to present for a vote the issuance by the Company of shares of common stock pursuant to the terms of the private placement financing transaction during the Company's Annual Meeting in June 2023.

On the tenth trading day following the announcement of the stockholder approval, each share of Series A-1 Preferred Stock shall automatically convert into a unit consisting of: (1) the number of shares of common stock equal to the quotient of (A) the liquidation preference with respect to such share of Series A-1 Preferred Stock, divided by (B) the conversion price, provided that, to the extent the share conversion would cause such Holder's beneficial ownership to exceed 9.99%, such holder shall receive shares of Series A-2 Preferred Stock in lieu of common stock, on a one-for-one basis, with respect to the number of shares of common stock that exceed 9.99% ownership, (2) a Tranche A Warrant, (3) a Tranche B Warrant, and (4) a Tranche C Warrant.

Redemption: In the event stockholder approval is not obtained within one year following the issuance of the Series A-1 Preferred Stock, at the election of the holder, shares of Series A-1 Preferred Stock shall be redeemed by the Corporation at a price equal to the then liquidation preference at any time for up to three years following the issuance date.

Liquidation Preference: The Series A-1 Preferred Stock shall have a liquidation preference of one-times the original per share price of $1,000 per share, plus any accrued but unpaid dividends thereon, whether or not declared, subject to certain customary anti-dilution adjustments.

The Series A-2, A-3, A-4, and A-5 Preferred Stock have the following rights:

Dividends: Dividends will accrue, on all issued and outstanding shares of Series A-2, A-3, A-4, and A-5 Preferred Stock, prior to and in preference to all other shares of capital stock of the Company, at an annual rate of eight percent (8%) compounded annually on the original per share price (plus any such accreted compounded amounts). If such dividends are not declared and paid in cash, the dividend amounts will be added to the aggregate liquidation preference then outstanding.

Voting: Holders of the Series A-2, A-3, A-4, and A-5 Preferred Stock are entitled to vote together with the common stock on an as-if-converted-to-common-stock basis as determined by dividing the liquidation preference with respect to such shares of Preferred Stock by the conversion price. Holders of common stock are entitled to one vote for each share of common stock held on all matters submitted to a vote of stockholders.

At the option of the holder thereof, each share of Series A-2 Preferred Stock, Series A-3 Preferred Stock, Series A-4 Preferred Stock, or Series A-5 Preferred Stock shall be convertible into one share of common stock.

11. Warrant Liability

In connection with the Preferred Stock Offering (see Note 10), the Company issued Warrants, which included Warrants to purchase Series A-3 Preferred Stock, Series A-4 Preferred Stock, and Series A-5 Preferred Stock.

The Warrants are recognized as liabilities in the balance sheets and were initially recognized at fair value at the time of issuance. The Warrants are also subject to remeasurement at each balance sheet date after issuance. Any change in fair value is recognized as a component of other income (expense) in the statements of operations in the period of change.

The valuation of the Warrants contained unobservable inputs that reflected the Company's own assumptions for which there was little market data. Accordingly, the Warrants were measured at fair value on a recurring basis using unobservable inputs and were classified as Level 3 inputs. The significant unobservable inputs used in the fair value measurement of the Company's Warrants include, but are not limited to, probability of obtaining certain shareholder approvals, probability of reaching certain technical milestones related to the development of Renazorb, and the estimated term of the Warrants. Significant increases (decreases) in any of those inputs in isolation would have resulted in a significantly higher (lower) fair value measurement. Generally, a change in the assumption used for the probability of obtaining certain shareholder approvals is not correlated to a change in the probability of reaching certain technical milestones. However, a change to the assumption used for the probability of obtaining certain shareholder approvals or a change in the probability of reaching certain technical milestones would have been accompanied by a directionally opposite change and a directionally similar change, respectively, in the assumption used for the estimated term.

The fair value of the contingently issuable warrants associated with the Company's March 2023 private placement transaction were determined by using a Monte Carlo simulation technique ("MCS") to value the embedded derivatives associated with the warrants. The MCS methodology calculates the theoretical value of a warrant based on certain parameters, including: (i) the threshold of exercising the warrant, (ii) the price of the underlying security, (iii) the time to expiration, or expected term, (iv) the expected volatility of the underlying security, (v) the risk-free rate, (vi) the number of paths, (vii) estimated probability assumptions surrounding shareholder approval as well as the achievement by the Company of technical milestones associated with our regulatory and commercial progress, and (viii) an estimated discount for lack of marketability.

These valuation techniques involve management's estimates and judgment based on unobservable inputs and are classified in Level 3. The fair value estimates may not be indicative of the amounts that would be realized in a market exchange. Additionally, there may be inherent uncertainties or changes in the underlying assumptions used, which could significantly affect the current or future fair value estimates. Generally, a significant increase (decrease) in the probabilities of shareholder approval and the achievement of technical milestones would have resulted in a significantly higher (lower) fair value measurement; however, changes in other inputs such as expected term and price of the underlying common stock will have a directionally opposite impact on fair value measurement.

The Company uses a third-party valuation expert to assist in the determination of the fair value of the Warrants. The tables below summarize the valuation inputs into the MCS model for the derivative liability associated with the three tranches of contingently issuable warrants on the date of signing of our private placement financing of March 3, 2023 and at March 31, 2023.

Tranche A Warrant	**At March 3, 2023**	**At March 31, 2023**
Fair value of underlying stock	$ 0.49	$ 2.10
Volatility	90.2% – 94.6%	109.5% – 128.2%
Risk free rate	4.7% – 5.0%	4.1% – 4.5%
Dividend yield	0%	0%
Term (in years)	1.3 – 2.3	1.3 – 2.3
Discount for lack of marketability	20%	25%
Probability for shareholder approval	45%	45%
Probability for FDA approval	16.0% – 31.9%	16.0% – 31.9%

Tranche B Warrant	At March 3, 2023	At March 31, 2023
Fair value of underlying stock	$ 0.49	$ 2.10
Volatility	93.7% – 95.8%	108.5% – 110.0%
Risk free rate	4.6% – 4.9%	3.9% – 4.3%
Dividend yield	0%	0%
Term (in years)	1.8 – 2.8	1.8 – 2.8
Discount for lack of marketability	20%	25%
Probability for shareholder approval	45%	45%
Probability for TDAPA approval	0% – 20.0%	0% – 20.0%

Tranche C Warrant	At March 3, 2023	At March 31, 2023
Fair value of underlying stock	$ 0.49	$ 2.10
Volatility	97.1% – 103.9%	103.6% – 109.8%
Risk free rate	4.5% – 4.6%	3.7% – 3.9%
Dividend yield	0%	0%
Term (in years)	2.8 – 3.8	2.8 – 3.8
Discount for lack of marketability	20%	25%
Probability for shareholder approval	45%	45%
Probability for commercialization	2.7% – 9.1%	2.7% – 9.1%

As of the issuance date (March 3, 2023), the Company estimated the fair value of the Warrants to be $2.8 million. As of March 31, 2023, the Company estimated the fair value of the Warrants to be $13.2 million.

The following table summarizes activity for the Company's contingently issuable preferred stock warrants for the three months ended March 31, 2023:

	Number of Shares Underlying Outstanding Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2022	-	-	-	-
Warrants contingently issuable	157,000,888	0.64	2.10	229,069
Warrants exercised	-	-	-	-
Outstanding, March 31, 2023	157,000,888	0.64	2.10	229,069

12. Stock-based Compensation

On July 15, 2021, in connection with the completion of the Company's IPO, the Company adopted a new comprehensive equity incentive plan, the 2021 Omnibus Equity Incentive Plan (the "2021 Plan"). Following the effective date of the 2021 Plan, no further awards may be issued under the 2018 Plan or the 2019 Plan (collectively, the "Prior Plans"). However, all awards under the Prior Plans that are outstanding as of the effective date of the 2021 Plan will continue to be governed by the terms, conditions and procedures set forth in the Prior Plans and any applicable award agreements. A total of 1,302,326 shares of common stock are reserved for issuance pursuant to the 2021 Plan. The 2021 Plan provides for the issuance of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards. As of December 31, 2022 and March 31, 2023, 352,938 shares of common stock are available under the 2021 Plan.

The following table summarizes activity for stock options under all plans for the three months ended March 31, 2023:

	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, 2022	1,342,670	$ 2.75	8.47	$ 52
Options granted	-			
Options forfeited	(4,000)	1.66	-	-
Options exercised	(2,181)	3.27	-	-
Outstanding, March 31, 2023	1,336,489	2.76	8.23	643
Options vested and exercisable as of March 31, 2023	709,899	$ 3.16	7.62	$ 208

As of March 31, 2023, the unrecognized compensation cost related to outstanding stock options was $0.9 million, which is expected to be recognized as expense over approximately 2.1 years.

During the year ended December 31, 2021, employees and consultants exercised a total of 383,721 stock options and the Company received $119,000 in proceeds. A portion of these options were exercised early (prior to vesting), and as of March 31, 2023, 7,365 of the options remained unvested. Proceeds received related to the unvested options of approximately $24,000 at March 31, 2023 were included in accrued liabilities on the accompanying balance sheet and will be reclassified to equity as vesting occurs, provided the employees and consultants continue to provide services to the Company. Proceeds received related to the vested portion of options of $7,000 were reclassified to equity during the three months ended March 31, 2023. The vested portion of the exercises was 376,349 shares at March 31, 2023.

During May 2022, the Company granted a consultant 10,000 restricted stock units with a grant date fair value of $7,200, resulting in a fair value per share of $0.72. Subject to the consultant's continued service, the restricted stock units shall vest upon the two-year anniversary of the date of grant. As of March 31, 2023, the unrecognized compensation cost related to the grant was approximately $4,000, which is expected to be recognized as expense over approximately 14 months.

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

The Company has recorded stock-based compensation expense, which includes expense related to restricted stock units, allocated by functional cost as follows for the three months ended March 31, 2022 and 2023 (in thousands):

	Three Months Ended March 31,	
	2022	2023
Research and development	$ 99	$ 82
General and administrative	191	62
Total stock-based compensation	$ 290	$ 144

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 underlying the Company's common stock is determined based on the public market closing price on each date of grant. The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of significant levels of management judgment.

Volatility - The expected volatility being used is derived from the historical stock volatilities of a representative industry peer group of comparable publicly listed companies over a period approximately equal to the expected term of the options.

Risk-free Interest Rate - The risk-free interest rate is based on median U.S. Treasury zero coupon issues with remaining terms similar to the expected term on the options.

Expected Dividend – Through March 31, 2023, the Company has never declared nor paid any cash dividends. The Company shall modify its dividend policy to state that the Company intends to pay dividends to all stockholders, including holders of Series A Preferred Stock on an as-if-converted-to-common-stock basis, on a quarterly basis in an amount of which the aggregate of all quarterly dividends shall equal at least seventy-five percent (75%) of its annual net cash flow from operations following the approval of Renazorb by the FDA if
obtained, and the commencement of commercial sales.

There were no equity awards granted to employees, directors and non-employees for the three months ended March 31, 2022 and 2023.

13. Net loss per share

The Company computes net loss per share using the two-class method. The two-class method uses an earnings allocation formula that determines net loss per share for common stock and any participating securities according to dividends declared and participation rights in undistributed earnings.

Diluted net loss per share includes the potential dilutive effect of common stock equivalents as if such securities were converted or exercised during the period, when the effect is dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock units; (ii) common stock to be issued upon the assumed exercise of the Company's common stock warrants; and (iii) prior to issuance, the contingently issuable warrants related to the Company's March private placement financing. Because the impact of these items is generally anti-dilutive during periods of net loss, there is no difference between basic and diluted loss per common share for periods with net losses.

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

	Three Months Ended March 31,	
	2022	2023
Numerator:		
Net loss	$ (3,537)	$ (14,575)
Less: Deemed dividends on Series A-1 Preferred Stock	-	(192)
Net loss attributable to common shares, basic and diluted	(3,537)	(14,767)
Denominator:		
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	15,004,617	15,232,406
Net loss per share attributable to common stockholders, basic and diluted	$ (0.24)	$ (0.97)

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 March 31,	
	2022	2023
Options to purchase common stock	1,187,085	1,336,489
Warrants to purchase common stock	4,784,193	4,784,193
Contingently issuable warrants to purchase convertible preferred stock	-	157,000,888
Total	5,971,278	163,121,570

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward Looking Statements

This Quarterly Report on Form 10-Q for the three-month period ended March 31, 2023 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.

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 Form 10-K. 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 $3.5 million and $14.6 million for the three months ended March 31, 2022 and 2023. As of March 31, 2023, we had an accumulated deficit of $48.6 million. We expect that our operating expenses will increase significantly as we advance our product candidates through pre-clinical and clinical development, seek regulatory approval, and prepare for and, if approved, proceed to commercialization; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel.

We have funded our operations primarily from the sale and issuance of common stock, convertible promissory notes and from a loan, including cash and deferred salary from our Chief Executive Officer and principal stockholder.

Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of our current product candidates and future product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into agreements to raise capital as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our current product candidates and future product candidates.

Recent Developments

On March 3, 2023, we entered into a securities purchase agreement (the "Purchase Agreement") with certain accredited investors (the "Investors"), pursuant to which we agreed to issue and sell, in a private placement (the "Offering"), 30,190 shares of Series A-1 Convertible Preferred Stock, par value $0.001 per share (the "Series A-1 Preferred Stock"), which offering will result in up to $130 million in gross proceeds and initial upfront funding of $30 million.

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

Subject to the terms and limitations contained in the Certificate of Designation, the Series A-1 Preferred Stock issued in the Offering will not become convertible until our stockholders approve the issuance of the Units upon conversion of the Series A-1 Preferred Stock and the issuance of all Common Stock upon conversion of the Series A Preferred Stock (as defined below), among other items (the "Stockholder Approval"). On the tenth (10th) Trading Day (as defined in the Certificate of Designation) following the announcement of the Stockholder Approval, each share of Series A-1 Preferred Stock shall automatically convert into a Unit. Subject to the limitations set forth in the Certificate of Designation, at the option of the holder, each share of Series A-2 Preferred Stock, Series A-3 Convertible Preferred Stock, Series A-4 Convertible Preferred Stock or Series A-5 Convertible Preferred Stock shall be convertible into one share of Common Stock.

In addition, in connection with the Offering, we agreed to modify our dividend policy to state that we intend to pay dividends to all stockholders, including holders of Series A Preferred Stock on an as-if-converted-to-Common-Stock basis, on a quarterly basis in an amount of which the aggregate of all quarterly dividends shall equal at least seventy-five percent (75%) of our annual net cash flow from operations following approval of Renazorb by the FDA, if obtained, and the commencement of commercial sales.

The COVID-19 Pandemic and its Impacts on Our Business

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

Components of Results of Operations

Revenues

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

Research and Development Expenses

Substantially all of our research and development expenses consist of expenses incurred in connection with the development of our product candidates. These expenses include fees paid to third parties to conduct certain research and development activities on our behalf, consulting costs, costs for laboratory supplies, product acquisition and license costs, certain payroll and personnel-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expenses for our research and product development employees and allocated overheads, including information technology costs and utilities and expenses for the issuance of shares pursuant to the anti-dilution clause in the purchase of in process research and development technology ("IPR&D"). We expense both internal and external research and development expenses as they are incurred.

We do not allocate our costs by product candidate, as a significant amount of research and development expenses include internal costs, such as payroll and other personnel expenses, laboratory supplies and allocated overhead, and external costs, such as fees paid to third parties to conduct research and development activities on our behalf, are not tracked by product candidate.

We expect our research and development expenses to increase substantially for at least the next few years, as we seek to initiate additional clinical trials for our product candidates, complete our clinical programs, pursue regulatory approval of our product candidates and prepare for the possible commercialization of such product candidates. Predicting the timing or cost to complete our clinical programs or validation of our commercial manufacturing and supply processes is difficult and delays may occur because of many factors, including factors outside of our control. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, we could be required to expend significant additional financial resources and time on the completion of clinical development. Furthermore, we are unable to predict when or if our product candidates will receive regulatory approval with any certainty.

General and Administrative Expenses

General and administrative expenses consist principally of payroll and personnel expenses, including salaries and bonuses, benefits and stock-based compensation expenses, professional fees for legal, consulting, accounting and tax services, including information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses.

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 of the change in fair value of our warrant liability, interest income and interest expense.

Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2023

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

	Three Months Ended March 31,			
	2022	2023	Change	% Change
	(unaudited)	(unaudited)		
Licensing revenues:	$ -	$ 675	$ 675	100%
Operating expenses:				
Research and development	1,933	3,030	1,097	57%
General and administrative	1,604	1,847	243	15%
Total operating expenses	3,537	4,877	1,340	38%
Loss from operations	(3,537)	(4,202)	(665)	19%
Other income (expenses):				
Interest income	-	14	14	100%
Interest expense	-	(12)	(12)	100%
Change in fair value of warrant liability	-	(10,375)	(10,375)	100%
Total other income (expenses)	-	(10,373)	(10,373)	100%
Net loss	$ (3,537)	$ (14,575)	$ (11,038)	312%

Licensing Revenues

Licensing revenues increased approximately $0.7 million, or 100%, from the three months ended March 31, 2022 due to an upfront payment of approximately $0.7 million associated with a licensing agreement entered into with Lotus International Pte Ltd. in February 2023. There was no comparable revenue earned in the prior period. We may earn additional licensing revenue in the future if we negotiate business development arrangements with third parties.

Research and Development Expenses

Research and development expenses increased by approximately $1.1 million, or 57%, from approximately $1.9 million for the three months ended March 31, 2022 to approximately $3.0 million for the three months ended March 31, 2023. The increase in research and development expenses was primarily due to a $962,000 increase in drug development costs. Labor costs increased $148,000 from the prior period. Consulting and other costs increased $7,000. Non-cash stock compensation decreased $17,000.

General and Administrative Expenses

General and administrative expenses increased by $243,000, or 15%, from approximately $1.6 million for the three months ended March 31, 2022 to approximately $1.8 million for the three months ended March 31, 2023 primarily due to an increase of $448,000 in consulting and professional services costs. Insurance expense for directors and officers decreased $166,000. Stock compensation costs decreased $129,000 from the prior period. Travel, rent, and other costs increased $90,000.

Other Income (Expenses)

Other income (expenses) increased by $10.4 million, or 100%, from $0 in the three months ended March 31, 2022 to $10.4 million for the three months ended March 31, 2023 due primarily to a change in fair value of our warrant liability.

Liquidity and Capital Resources

Sources of Liquidity

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

As a result of our initial public offering ("IPO"), on July 13, 2021 we began trading on the Nasdaq Capital Market under the symbol "UNCY", and on July 15, 2021 we received approximately $22.3 million in net proceeds after deducting the underwriting discounts, commissions and offering expenses. We have used the net proceeds from the IPO to complete pre-clinical and clinical studies, submit regulatory filings to the FDA, and for general and corporate purposes, including hiring additional management and conducting market research and other commercial planning.

Future revenue streams may consist of collaboration or licensing revenue as well as product sales. We have generated approximately $0.7 million in licensing revenue during the three months ended March 31, 2023.

On March 3, 2023, we entered into a securities purchase agreement with certain healthcare-focused institutional investors that will provide up to $130.0 million in gross proceeds through a private placement and that includes initial upfront funding of $30.0 million. Proceeds from the offering will be used to support our NDA submission with the FDA for approval of Renazorb for the treatment of hyperphosphatemia in the U.S. and, if approved, for the commercial launch of Renazorb in the U.S.

Future Funding Requirements

We have incurred net losses since our inception. For the three months ended March 31, 2023, we had a net loss of $14.6 million, and we expect to incur substantial additional losses in future periods. As of March 31, 2023, we had an accumulated deficit of $48.6 million.

We expect to continue incurring losses in the future and will be required to raise additional capital in the future to complete our clinical trials, pursue product development initiatives and penetrate markets for the sale of our products. We believe that we will continue to have access to capital resources through possible equity offerings, debt financings, corporate collaborations or other means. There can be no assurance that we will be able to obtain additional financing on terms acceptable to us, on a timely basis or at all. If we are unable to secure additional capital, we may be required to curtail any clinical trials and development of new or existing products and take additional measures to reduce expenses in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. Based on our current level of expenditures, and after receiving the net proceeds of $28.0 million from a private placement financing, we believe that we have sufficient resources such that there is not substantial doubt about our ability to continue operations for at least one year after the date that these financial statements are available to be issued.

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

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

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

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

Related Party Payable

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

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):

	Three Months Ended March 31,	
	2022	**2023**
	(unaudited)	(unaudited)
Net cash (used in) provided by:		
Operating activities	$ (2,957)	$ (3,920)
Investing activities	(2)	-
Financing activities	-	27,797
Net increase (decrease) in cash and cash equivalents	$ (2,959)	$ 23,877

Cash Flows from Operating Activities

Net cash used in operating activities was $3.9 million for the three months ended March 31, 2023. Cash used in operating activities was primarily due to the use of funds for development costs associated with our drug candidates, labor costs, consulting services, and other corporate expenditures for investor relations, compliance, and legal services.

Net cash used in operating activities was $3.0 million for the three months ended March 31, 2022. Cash used in operating activities was primarily due to the use of funds for development costs associated with our drug candidates, labor costs, consulting services, and other corporate expenditures for investor relations, compliance, and legal services.

Cash Flows from Investing Activities

Net cash used in investing activities was $2,000 for the three months ended March 31, 2022 and was due to the purchase of furniture and fixtures for our corporate office. There were no comparable fixed asset purchases during the current three month period.

Cash Flows from Financing Activities

Net cash provided by financing activities was $27.8 million during the three months ended March 31, 2023 due primarily to the private placement financing agreement we signed on March 3, 2023.

There were no cash flows provided by financing activities during the three months ended March 31, 2022.

Critical Accounting Policies, Significant Judgments and Use of Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We consider our critical accounting policies and estimates to be related to revenue, research and development, stock-based compensation, and warrant liabilities. The fair value of warrants contingently issued as part of our March 2023 private placement financing represent a material addition to our critical accounting policies and estimates. There have been no other material changes to our critical accounting policies and estimates during the three months ended March 31, 2023 from those used for the year ended December 31, 2022. The below policies represent our critical accounting policies.

Revenue Recognition

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

Warrant Liabilities

In conjunction with the issuance of Series A-1 Preferred Stock (see Note 10), we established a warrant liability as of March 3, 2023, representing the fair value of warrants that may be issued, subject to shareholder approval, upon conversion of the Series A-1 Preferred Stock. We account for these warrants as liabilities (in accordance with ASC 480) on the balance sheets as a result of certain redemption clauses that are not within the control of the Company. The warrant liabilities are initially measured at fair value, resulting in an implied discount on the related preferred stock financing arrangement (recognized as a partial offset to the carrying value of the Series A-1 Preferred Stock), and are remeasured at fair value each reporting period. Changes in the fair value of the warrant liabilities are recognized in earnings during each period. The warrant liabilities are measured using Level 3 fair value inputs. See Note 11 for a description of warrant liabilities and the related valuations.

Research and Development

We expense costs when incurred related to the research and development associated with the design, development and testing of product candidates, as well as acquisition of product candidates or compounds. Research and development expenses include fees paid to third parties to conduct certain research and development activities on our behalf, consulting costs, costs for laboratory supplies, product acquisition and license costs, certain payroll and personnel-related expenses, including salaries and bonuses, employee benefit costs and stock-based compensation expenses for our research and product development employees and allocated overheads, including information technology costs and utilities and expenses for issuance of shares pursuant to anti-dilution clause in the purchase of IPR&D technology. We expense both internal and external research and development expenses as they are incurred.

Stock-Based Compensation

We account for stock-based compensation for all share-based payments made to employees and non-employees by estimating the fair value on the date of grant and recognizing compensation expense over the requisite service period on a straight-line basis. We recognize forfeitures related to stock-based compensation as they occur. We estimate the fair value of stock options using the Black-Scholes option-pricing model. The Black-Scholes model requires the input of subjective assumptions, including expected common stock volatility, expected dividend yield, expected term, and the risk-free interest rate.

JOBS Act 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 these exemptions, including, without limitation, (i) providing an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with the requirement adopted by the Public Company Accounting Oversight Board ("PCAOB") regarding the communication of critical audit matters in the auditor's report on financial statements. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Recent Accounting Pronouncements

See 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

As a smaller reporting company, we are not required to provide the information required by this item.

ITEM 4. CONTROLS AND PROCEDURES

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of the Company's management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our 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 our disclosure controls and procedures were not effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit 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 our management, including our 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 March 31, 2023. Specifically, we lack a sufficient number of professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately while maintaining appropriate segregation of duties. Without such professionals, we did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries.

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

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

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

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

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

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with the evaluation that occurred during the quarter ended March 31, 2023 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

We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition. We may periodically be the subject of various pending or threatened legal actions and claims arising out of our operations in the normal course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us 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, adequate provision has been made in our financial statements at March 31, 2023 with respect to such matters.

ITEM 1A. RISK FACTORS

There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2022.

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 Executive Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
31.2	Certification of Principal Financial Officer required under Rule 13a-14(a)/15d-14(a) under the Exchange Act.
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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 May, 2023.

Signature	Title	Date
/s/ Shalabh Gupta Shalabh Gupta	Chief Executive Officer, President and Chairman *(Principal Executive Officer)*	May 16, 2023
/s/ John Townsend John Townsend	Chief Financial Officer *(Principal Financial and Accounting Officer)*	May 16, 2023

Exhibit 31.1

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

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

(1) I have reviewed this Form 10-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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: May 16, 2023

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

Exhibit 31.2

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

I, John Townsend, certify that:

(1) I have reviewed this Form 10-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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: May 16, 2023

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

Exhibit 32.1

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

In connection with the Quarterly Report of Unicycive Therapeutics, Inc. (the "Company") on Form 10-Q for the three month period ended March 31, 2023, as filed with the Securities and Exchange Commission on May 16, 2023 (the "Report"), I, Shalabh Gupta, M.D., Chief Executive Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

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

Exhibit 32.2

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

In connection with the Quarterly Report of Unicycive Therapeutics, Inc. (the "Company") on Form 10-Q for the three month period ended March 31, 2023, as filed with the Securities and Exchange Commission on May 16, 2023 (the "Report"), I, John Townsend, Chief Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

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

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