# 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 September 30, 2021**

**OR**

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

**For the transition period from ____ to ____**

**Commission file number: 001-40582**

# UNICYCIVE THERAPEUTICS, INC.
*(Exact name of Registrant as specified in its charter)*

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

**5150 El Camino Real, Suite A-32**
**Los Altos, CA 94022**
**(650) 351-4495**
*(Address and telephone number of 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 November 10, 2021, there were 14,972,552 shares of the Company's common stock, par value $0.001 per share, issued and outstanding.

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## FORWARD LOOKING STATEMENTS

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

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

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



## PART I – FINANCIAL INFORMATION

### ITEM 1. FINANCIAL STATEMENTS

**Unicycive Therapeutics, Inc.**

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

| | As of December 31, 2020 | As of September 30, 2021 (unaudited) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash | $ - | $ 18,011 |
| Prepaid related party service fee | - | 58 |
| Deferred offering costs | 200 | - |
| Prepaid expenses and other current assets | 4 | 1,713 |
| Total current assets | 204 | 19,782 |
| Total assets | $ 204 | $ 19,782 |
| | | |
| **Liabilities and stockholders' (deficit) equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 184 | $ 49 |
| Related party service fee payable | 9 | - |

| | | |
|---|---|---|
| Accrued liabilities | 168 | 633 |
| Convertible notes | 1,528 | - |
| Loan from stockholder | 967 | 103 |
| Government loan | 19 | - |
| Total current liabilities | 2,875 | 785 |
| Total liabilities | 2,875 | 785 |
| Commitments and contingencies (Note 7) | | |
| Stockholders' (deficit) equity: | | |
| Preferred stock: $0.001 par value per share—10,000,000 shares authorized at December 31, 2020 and September 30, 2021 (unaudited); no shares issued and outstanding at December 31, 2020 and September 30, 2021 (unaudited) | $ - | $ - |
| Common stock, $0.001 par value per share – 200,000,000 shares authorized at December 31, 2020 and September 30, 2021 (unaudited); 8,514,070 shares issued and outstanding at December 31, 2020, and14,972,552 shares issued and outstanding at September 30, 2021 (unaudited) | 9 | 15 |
| Additional paid-in capital | 3,242 | 32,169 |
| Accumulated deficit | (5,922) | (13,187) |
| Total stockholders' (deficit) equity | (2,671) | 18,997 |
| Total liabilities and stockholders' (deficit) equity | $ 204 | $ 19,782 |

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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2021 | 2020 | 2021 |
| Operating expenses: | | | | |
| Research and development | $ 304 | $ 3,776 | $ 633 | $ 4,719 |
| General and administrative | 322 | 939 | 670 | 1,506 |
| Total operating expenses | 626 | 4,715 | 1,303 | 6,225 |
| Loss from operations | (626) | (4,715) | (1,303) | (6,225) |
| Other expenses: | | | | |
| Interest expense | (76) | (55) | (81) | (628) |
| Loss on debt conversion | - | (431) | - | (431) |
| Gain on extinguishment of debt | - | - | - | 19 |
| Total other expenses | (76) | (486) | (81) | (1,040) |
| Net loss | $ (702) | $ (5,201) | $ (1,384) | $ (7,265) |
| Net loss per share, basic and diluted | $ (0.08) | $ (0.37) | $ (0.16) | $ (0.69) |
| Weighted-average shares outstanding used in computing net loss per share, basic and diluted | 8,514,070 | 14,167,098 | 8,494,858 | 10,538,473 |

See accompanying notes to the financial statements



**Unicycive Therapeutics, Inc.**

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

| | Common Stock | | Preferred stock | | Additional Paid-In | Accumulated | Total Stockholders' (Deficit) |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Deficit | Equity |
| **Balance at December 31, 2019** | 8,456,179 | $ 8 | - | $ - | $ 2,766 | $ (3,658) | $ (884) |
| Net loss (unaudited) | - | - | - | - | - | (344) | (344) |
| Issuance of common stock for cash (unaudited) | 11,862 | - | - | - | 50 | - | 50 |
| Issuance of common stock for anti-dilution clause (unaudited) | 475 | - | - | - | 2 | - | 2 |
| Stock-based compensation expense (unaudited) | - | - | - | - | 31 | - | 31 |
| **Balance at March 31, 2020 (unaudited)** | 8,468,516 | 8 | - | - | 2,849 | (4,002) | (1,145) |
| Net loss (unaudited) | - | - | - | - | - | (338) | (338) |
| Issuance of common stock for cash (unaudited) | 21,401 | 1 | - | - | 91 | - | 92 |
| Issuance of common stock for anti-dilution clause (unaudited) | 6,624 | - | - | - | 28 | - | 28 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Stock-based compensation expense (unaudited) | - | - | - | - | 60 | - | 60 |
| **Balance at June 30, 2020 (unaudited)** | 8,496,541 | 9 | - | - | 3,028 | (4,340) | (1,303) |
| Net loss (unaudited) | - | - | - | - | - | (702) | (702) |
| Issuance of common stock for anti-dilution clause (unaudited) | 17,529 | - | - | - | 74 | - | 74 |
| Stock-based compensation expense (unaudited) | - | - | - | - | 71 | - | 71 |
| **Balance at September 30, 2020 (unaudited)** | 8,514,070 | $ 9 | - | $ - | $ 3,173 | $ (5,042) | $ (1,860) |

| | Common Stock | | Preferred stock | | Additional Paid-In | Accumulated | Total Stockholders' (Deficit) |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Capital | Deficit | Equity |
| **Balance at December 31, 2020** | 8,514,070 | $ 9 | - | $ - | $ 3,242 | $ (5,922) | $ (2,671) |
| Net loss (unaudited) | - | - | - | - | - | (964) | (964) |
| Issuance of common stock for exercise of options (unaudited) | 233,819 | - | - | - | 31 | - | 31 |
| Stock-based compensation expense (unaudited) | - | - | - | - | 202 | - | 202 |
| **Balance at March 31, 2021 (unaudited)** | 8,747,889 | 9 | - | - | 3,475 | (6,886) | (3,402) |
| Net loss (unaudited) | - | - | - | - | - | (1,100) | (1,100) |
| Issuance of common stock for exercise of options (unaudited) | 23,401 | - | - | - | 6 | - | 6 |
| Stock-based compensation expense (unaudited) | - | - | - | - | 294 | - | 294 |
| **Balance at June 30, 2021 (unaudited)** | 8,771,290 | 9 | - | - | 3,775 | (7,986) | (4,202) |
| Net loss (unaudited) | - | - | - | - | - | (5,201) | (5,201) |
| Issuance of common stock for cash, net of $2.7 million offering costs (unaudited) | 5,000,000 | 5 | - | - | 22,266 | - | 22,271 |
| Conversion of convertible notes into common stock (unaudited) | 736,773 | 1 | - | - | 3,684 | - | 3,685 |
| Issuance of common stock for exercise of options (unaudited) | 26,115 | - | - | - | 14 | - | 14 |
| Issuance of common stock for anti-dilution clause (unaudited) | 438,374 | - | - | - | 2,191 | - | 2,191 |
| Stock-based compensation expense (unaudited) | - | - | - | - | 239 | - | 239 |
| **Balance at September 30, 2021 (unaudited)** | 14,972,552 | $ 15 | - | $ - | $ 32,169 | $ (13,187) | $ 18,997 |

See accompanying notes to the financial statements



**Unicycive Therapeutics, Inc.**

**Statements of Cash Flows**
**(in thousands)**
**(Unaudited)**

| | Nine Months Ended September 30, 2020 | Nine Months Ended September 30, 2021 |
|---|---|---|
| **Cash flows from operating activities** | | |
| Net loss | $ (1,384) | $ (7,265) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| R&D Expense for issuance of common stock for anti-dilution clause | 104 | 2,191 |
| Stock-based compensation expense | 161 | 735 |
| Convertible debt discount amortization | 59 | 488 |
| Convertible debt non-cash interest | 17 | 139 |
| Gain on extinguishment of debt | - | (19) |
| Deferred compensation to CEO | 320 | 249 |
| Loss on debt conversion | - | 431 |
| Changes in assets and liabilities: | | |
| Prepaid expense and other current assets | (11) | (1,709) |
| Prepaid related party service fee | - | (58) |
| Accounts payable and accrued liabilities | (88) | 463 |
| Related party service fee payable | (99) | (9) |
| Net cash used in operating activities | (921) | (4,364) |
| **Cash flows from financing activities** | | |
| Net proceeds from initial public offering | - | 22,271 |
| Issuance of common stock for cash | 142 | - |
| Proceeds from loan from stockholder | 150 | 248 |
| Proceeds from convertible notes | 900 | 1,098 |
| Repayment of loan from stockholder | (150) | (1,361) |
| Deferred offering costs | (92) | - |
| Proceeds from exercise of options | - | 119 |
| Proceeds from government loan | 19 | - |
| Net cash provided by financing activities | 969 | 22,375 |
| Net increase in cash | 48 | 18,011 |
| Cash at the beginning of the period | 15 | - |

| | | |
|---|---|---|
| Cash at the end of the period | $ 63 | $ 18,011 |
| **Supplemental cash flow information** | | |
| Deferred offering costs included in accrued liabilities | $ 50 | $ - |
| Cash paid for income taxes | $ 1 | $ - |

See accompanying notes to the financial statements



**Unicycive Therapeutics, Inc.**

**Notes to the Financial Statements (unaudited)**

**1. Organization and Description of Business**

**Overview**

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

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

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

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

**Liquidity**

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, development by competitors of new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with governmental regulations and the need to obtain additional financing to fund operations. The Company's product candidates currently under development will require significant additional research and development efforts prior to commercialization. The Company has not generated revenue to date.

The Company has incurred operating losses and negative cash flows from operations since inception and expects to continue to incur negative cash flows from operations for the foreseeable future. As the Company increases its research and development activities, the operating losses are expected to increase. The Company has historically relied on private equity offerings, debt financings and loans from a stockholder to fund its operations. As of September 30, 2021 and December 31, 2020, the Company had an accumulated deficit of $13.2 million and $5.9 million, respectively.

As a result of its initial public offering ("IPO"), on July 13, 2021 the Company began trading on the Nasdaq Capital Market under the symbol "UNCY", and on July 15, 2021 received approximately $22,271,000 in net proceeds after deducting the underwriting discounts, commissions and other offering expenses. The Company intends to use the net proceeds from the IPO to complete pre-clinical and clinical studies, submit regulatory filings to the FDA, and for general and corporate purposes, including hiring additional management and conducting market research and other commercial planning.

The Company expects to continue incurring losses for the foreseeable future and will be required to raise additional capital in the future to complete its planned clinical trials, pursue product development initiatives and penetrate markets for the sale of its products. Management believes that the Company will continue to have access to capital resources through possible equity offerings, debt financings, corporate collaborations or other means. From January 2021 through May 2021, the Company received an aggregate of $1.1 million upon the issuance of convertible notes. These funds were used primarily to settle outstanding accounts payable as well as $160,000 of the loan outstanding from the chief executive officer and principal stockholder. In addition, the Company received approximately $22,271,000 in net proceeds from its IPO. There can be no assurance that the Company will be able to obtain additional financing on terms acceptable to the Company, on a timely basis or at all. If the Company is unable to secure additional capital, it may be required to curtail any clinical trials and development of new or existing products and take additional measures to reduce expenses in order to conserve its cash in amounts sufficient to sustain operations and meet its obligations. Based on the Company's current level of expenditures, and given the Company's cash balance of $18,011,000 as of September 30, 2021, the Company believes that it has sufficient resources to continue operations for at least one year after the date that these financial statements are available to be issued.



**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

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

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

**Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the periods presented. Management believes that these estimates and assumptions are reasonable; however, actual results may differ and could have a material effect on future results of operations and financial position. Significant items subject to such estimates and assumptions include deferred tax asset valuation allowance, unrecognized tax benefits, stock-based compensation and fair value of Company's common stock. Actual results may materially differ from those estimates.

**Segment Information**

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

**Risks and Uncertainties**

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

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

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

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



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

**Deferred Offering Costs**

Deferred offering costs, consisting of legal, accounting and other fees and costs relating to the Company's Initial Public Offering ("IPO") are capitalized and recorded as a current asset on the balance sheets. There were $0.2 million of deferred offering costs capitalized as of December 31, 2020. As of September 30, 2021, all previously deferred offering costs, totaling approximately $0.9 million, were netted against the proceeds received upon the closing of the IPO, which occurred on July 15, 2021.

**Fair Value of Financial Instruments**

The Company's financial instruments include cash, prepaid expenses, accounts payable, convertible notes and a loan from the Chief Executive Officer and stockholder of the Company. The carrying amounts of these items approximate fair value as of December 31, 2020 and September 30, 2021 due to their short-term nature.

**Concentration of Credit Risk**

Financial instruments that potentially subject the Company to concentration of credit risk consist of cash. All of the Company's cash was deposited in one account at a financial institution, and the account balance may at times exceed federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institution in which the cash is held.

**Prepaid Expenses**

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

**Research and Development Expenses**

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

**General and Administrative Expenses**

General and administrative expenses represent personnel costs for employees involved in general corporate functions, including finance, accounting, legal and human resources, among others. Additional costs included in general and administrative expenses consist of professional fees for legal (including patent costs), audit and other consulting services, stock-based compensation and other general corporate overhead expenses as well as costs from a service agreement with a related party (See Note 6).



**Patent Costs**

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

**Stock-Based Compensation**

The Company accounts for stock-based compensation for all share-based payments made to employees and non-employees by estimating the fair value on the date of grant and recognizing compensation expense over the requisite service period on a straight-line basis. The Company recognizes forfeitures related to stock-based compensation as they occur. The Company estimates the fair value of stock options using the Black-Scholes option-pricing model. The Black-Scholes model requires the input of subjective

assumptions, including expected common stock volatility, expected dividend yield, expected term, risk-free interest rate, and the estimated fair value of the underlying common stock on the date of grant.

**Common Stock Valuations**

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

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

**Income Taxes**

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

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



**Comprehensive Loss**

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

**Net Loss per Share**

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, common stock options and warrants are considered to be potentially dilutive securities. Basic and diluted net loss per share is presented in conformity with the two-class method required for participating securities. The Company has no participating securities and as such, the net loss was attributed entirely to common stockholders. As the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods. All common share amounts and per share amounts have been adjusted to reflect a 1-for-4.3 reverse stock split of the Company's common stock that was effectuated on June 21, 2021.

**Recent Accounting Pronouncements**

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

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

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). This ASU requires a lessee to recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the leases with a term of greater than 12 months. This ASU is effective for the Company's fiscal years beginning after December 15, 2021, with early adoption permitted. The Company has adopted this standard effective as of January 1, 2019. The Company chose to adopt the package of practical expedients available from the FASB. As a policy election, the Company chose to expense and amortize, on a straight line, the leases with terms less than 12 months. The adoption of this standard did not have a material effect on the Company's financial statements.

**3. Significant Agreements**

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



In October 2017, the Company entered into an exclusive license agreement with Sphaera, a stockholder, for the rights to further develop the drug candidate, UNI 494, for commercialization. No payments were made upon execution of the agreement but rather payments for $50,000 will be due commencing with the initiation by the Company of

a second clinical trial and $50,000 on completion of such trial. At the time the FDA accepts a NDA application submitted by the Company for the product, the Company will pay Sphaera $1.65 million. Upon commercialization and sale of the drug product, royalty payments will also be payable quarterly to Sphaera equal to 2% of net sales on the preceding quarter.

In September 2018, the Company entered into an Assignment and Asset Purchase Agreement with Spectrum Pharmaceuticals, Inc. ("Spectrum Agreement") pursuant to which the Company purchased certain assets from Spectrum, including Spectrum's right, title, interest in and intellectual property related to Renazorb RZB 012, also known as RENALAN™ ("Renalan") and RZB 014, also known as SPI 014 ("SPI" and together with Renalan, the "Compounds"), to further develop and commercialize Renazorb and related compounds. In partial consideration for the Spectrum Agreement, the Company issued 313,663 shares of common stock to Spectrum valued at approximately $4,000 which represented four percent of the Company on a fully-diluted basis at the date of the execution of the Spectrum Agreement. The Spectrum Agreement has an anti-dilution provision, which provides that Spectrum maintain its ownership interest in the Company at 4% of the Company's shares on a fully-diluted basis. Fully-diluted shares of common stock for purposes of the Renazorb Purchase Agreement assumes conversion of any security convertible into or exchangeable or exercisable for common stock or any combination thereof, including any common stock reserved for issuance under a stock option plan, restricted stock plan, or other equity incentive plan approved by the Board of Directors of the Company immediately following the issuance of additional shares of the Company's common stock (but prior to the issuance of any additional shares of common stock to Spectrum). Spectrum's ownership shall not be subject to dilution until the earlier of thirty-six months from the first date the Company's stock trades on a public market, or the date upon which the Company attains a public market capitalization of at least $50 million. As part of the anti-dilution clause, the Company issued 149,762 and 105,897 shares of common stock during the years ended December 31, 2019 and 2020, respectively. The Company recognized $145,000 and $104,000 for the years ended December 31, 2019 and 2020, respectively, as research and development expenses as cost to issue those shares. 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 represents the final anti-dilution calculation required under the Spectrum Agreement, and no further anti-dilution shares will be issued. The Company calculated the fair value of the shares and recognized $2.2 million to research and development expenses as cost to issue those shares during the three and nine months ended September 30, 2021. The Company is also required to pay Spectrum 40% of all of the Company's sublicense income for any sublicense granted to certain sublicensees during the first 12 months after the Closing Date (as that term is defined in the Renazorb Purchase Agreement) and 20% of all other sublicense income. The Company's payment obligations to Spectrum will expire on the twentieth ($20^{th}$) anniversary of the Closing Date of the Renazorb Purchase Agreement.

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



**4. Balance Sheet Components**

Accounts payable as of December 31, 2020 and September 30, 2021 consisted of the following (in thousands):

| | As of December 31, 2020 | As of September 30, 2021 |
|---|---|---|
| | | (unaudited) |
| Trade accounts payable | $ 183 | $ 43 |
| Credit card liability | 1 | 6 |
| Total | $ 184 | $ 49 |

**5. Debt**

**Convertible Notes**

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

The Company has accounted for the 2021 Notes as stock-settled debt and was accreting the carrying amount of the 2021 Notes to the settlement amount through maturity.

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

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

As a result of the Company's initial public offering on July 13, 2021, approximately $2,387,000 of principal and $191,000 of unpaid accrued interest related to the 2021 and 2020 Notes was converted into shares of common stock. Additionally the noteholders were granted warrants equal to 25% of the conversion shares issued. The conversion resulted in a loss of $431,000 that is included as loss on debt conversion in the accompanying statements of operations for the three and nine months ended September 30, 2021.

In 2017 and 2018, the Company raised $550,000 from the issuance of twelve convertible promissory notes (the "2018 Notes"). The 2018 Notes bear interest at 10% per annum which was payable at maturity. The 2018 Notes' principal and interest were due and payable on written demand by the majority of the 2018 Note holders on the two-year anniversary of the first 2018 Note issued. The first 2018 Note was issued on October 5, 2017 and, accordingly, all 2018 Notes would have matured on October 5, 2019.

In the event the Company consummated an equity financing with an aggregate sales price of not less than $500,000, then the aggregate outstanding principal and unpaid interest would automatically convert into shares of the Company's common stock. The per-share price of the conversion would be equal to 75% of the price per share paid by the cash purchasers of the common stock sold in the financing.



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

**Paycheck Protection Program Loan**

On April 23, 2020, the Company entered into an $18,000 loan with Silicon Valley Bank pursuant to the Small Business Administration's ("SBA") Paycheck Protection Program ("PPP") as well as a $1,000 loan pursuant to the Economic Injury Disaster Assistance Program. The PPP loan proceeds are intended to be used for payroll over the eight-week period following the date of the loan. The loan terms provide that no principal or interest payments are due and interest will accrue at 1% per annum commencing on April 23, 2020 through October 23, 2020 (deferral period). Commencing one month after the deferral period and continuing monthly through the maturity of the loan on April 23, 2022, equal monthly payments of principal and interest are due. The Company classified the loans as a current liability, has applied for and received loan forgiveness in February 2021, and recorded a gain on extinguishment of debt in the statement of operations for the nine months ended September 30, 2021.

**6. Related Party Transactions**

**Loan from Chief Executive Officer and Stockholder**

The Company received advances from the stockholder of $248,000 during the nine months ended September 30, 2021. The Company repaid amounts owed to the stockholder of $1,361,000 during the nine months ended September 30, 2021. As of September 30, 2021 and December 31, 2020, the current liability loan from a stockholder of approximately $103,000 and $967,000, respectively, represents primarily the accumulation of deferred compensation due to the chief executive officer and stockholder. This amount bears no interest and is repayable on demand.

**Service agreement with Globavir**

On July 1, 2017, as amended on April 6, 2020, the Company entered into a Service Agreement with Globavir Biosciences, Inc. ("Globavir"), a related party (the "Service Agreement"). Globavir provides administrative and consulting services and shared office space and other costs in connection with the Company's drug development program. The Service Agreement provides Globavir the right to receive $50,000 per month for such services through December 31, 2019 and $10,000 per month commencing on January 1, 2020. As of December 31, 2020, $9,000 was payable to Globavir for such service fees. As of September 30, 2021, $58,000 was prepaid to Globavir for such service fees. Amounts incurred by the Company under the Service Agreement were $30,000, $30,000, $90,000 and $90,000 for the three and nine months ended September 30, 2020 and September 30, 2021, respectively, and are included in operating expenses in the statements of operations. The initial amended term of the agreement ended on December 31, 2020, and unless terminated, the Service Agreement automatically renews for successive one month periods after the initial termination date.



**Common stock purchase agreement and services agreement**

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

**7. Commitments and Contingencies**

**Contingencies**

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

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

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

**Indemnifications**

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

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

Additionally, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at the

Company's request in such capacity. The indemnification period covers all pertinent events and occurrences during the director's or officer's service.



**8. Stockholders' (Deficit) Equity**

**Authorized Common Stock**

The Company is authorized to issue up to 200,000,000 shares of common stock at par value of $0.001 per share.

**Issuance of Common Stock and Warrants**

During July 2021, as a result of its 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, convertible noteholders were granted a total of 184,193 common stock warrants with a 5-year term and with an exercise price of $6.00 per warrant.

The following table summarizes activity for warrants for the nine months ended September 30, 2021:

| | Number of Shares Underlying Outstanding Warrants | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (in Years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| **Outstanding, December 31, 2020** | - | - | - | - |
| Warrants granted | 4,784,193 | 6.00 | 4.79 | - |
| Warrants exercised | - | - | - | - |
| **Outstanding, September 30, 2021** | 4,784,193 | 6.00 | 4.79 | - |

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

During the nine months ended September 30, 2021, employees and consultants exercised a total of 383,721 stock options and the Company received $119,000 in proceeds. A portion of these options were exercised early (prior to vesting), and as of September 30, 2021, 100,388 of the options remained unvested. Proceeds received related to the unvested options of $68,000 at September 30, 2021 were recorded in accrued liabilities on the accompanying balance sheets and will be reclassified to equity as vesting occurs, provided the employees and consultants continue to provide services to the Company. The vested portion of the exercises was 283,335 shares at September 30, 2021.

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

During the year ended December 31, 2020, the Company issued 33,263 shares to investors in exchange of cash at $4.21 per share and 24,627 shares to Spectrum following its anti-dilution provision (Note 3).

**Voting Rights of Common Stock**

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

**Preferred Stock**

As of December 31, 2020 and September 30, 2021, the Company had 10,000,000 shares of preferred stock authorized, par value of $0.001 per share and no shares of preferred stock were issued or outstanding.



**9. Stock-based Compensation**

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

In October 2019, the Company adopted the 2019 Stock Option Plan ("2019 Plan") which allowed for the granting of incentive stock options ("ISO"), non-qualified stock options ("NSO") to the employees, members of the board of directors and consultants of the Company. In 2019 and during the first seven months of 2020, the Company granted ISOs and NSOs to consultants and directors from the 2019 Plan. As of December 31, 2019, 232,558 shares were authorized for issuance and 75,581 shares were available for future grant under the 2019 Plan. On April 6, 2020 the Company increased the shares authorized for issuance to 348,837 shares total. On February 17, 2021, the Company increased the shares authorized for issuance to 1,767,442 shares total. As of September 30, 2021, no further awards may be issued under the 2019 Plan.

In 2018, the Company adopted the 2018 Equity Incentive Plan ("2018 Plan") which allowed for the granting of incentive stock options ("ISO"), non-qualified stock options ("NSO"), stock appreciation rights, restricted stock and restricted stock units to the employees, members of the board of directors and consultants of the Company. In 2018, the Company granted ISOs and NSOs to consultants and directors from this plan. As of December 31, 2020, 465,116 shares were authorized for issuance and 17,442 shares were available for future grant under the 2018 Plan. As of September 30, 2021, no further awards may be issued under the 2018 Plan.

During July 2021, in connection with the appointment of Dr. Brigitte Schiller to the Company's board of directors, the Company granted Dr. Schiller 17,882 stock options with a ten year term, an exercise price of $5.00 per option, and a total fair value of $50,000 on the date of grant. Additionally, the Company granted Dr. Schiller 26,738 restricted stock units with a grant date fair value of $100,000. Subject to Dr. Schiller's continued service, such options and restricted stock units shall vest upon the one-year anniversary of the date of grant. As of September 30, 2021, the unrecognized compensation cost related to outstanding restricted stock units was $0.1 million, which is expected to be recognized as expense over approximately 9 months.

The following table summarizes activity for stock options under all plans for the nine months ended September 30, 2021:

| | Number of Shares Underlying Outstanding Options | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (in Years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| **Outstanding, December 31, 2020** | 786,047 | 1.42 | 8.28 | 2,201 |
| Options granted | 319,745 | 5.83 | | |
| Options exercised | (283,335) | 0.18 | | |
| **Outstanding, September 30, 2021** | 822,457 | 3.56 | 8.05 | 504 |
| | | | | |
| Shares vested and exercisable as of September 30, 2021 | 273,421 | $ 3.30 | 8.10 | $ 232 |

The grant date fair value of options granted during the nine months ended September 30, 2021 was $1.3 million.



As of September 30, 2021, the unrecognized compensation cost related to outstanding stock options was $1.5 million, which is expected to be recognized as expense over approximately 2.7 years.

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 and nine months ended September 30, 2020 and 2021 (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2021 | 2020 | 2021 |
| Research and development | $ 56 | $ 167 | $ 117 | $ 623 |
| General and administrative | 15 | 72 | 44 | 112 |
| Total stock-based compensation | $ 71 | $ 239 | $ 161 | $ 735 |

**Fair Value of Stock Options**

The assumptions are based on the following for each of the periods presented:

**Expected Term** - The expected term is calculated using the simplified method which is used when there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method.

**Common Stock Fair Value** - The fair value of the common stock underlying the Company's stock options prior to the initial public offering was estimated at each grant date and was determined on a periodic basis and based either on transactions with third parties in which common stock was sold for cash or with the assistance of an independent third-party valuation expert. The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of significant levels of management judgment.

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

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

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

The following averaged assumptions were used to calculate the fair value of awards granted to employees, directors and non-employees for the nine months ended September 30, 2020 and 2021:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2020 | 2021 |
| Expected volatility | 114.00% | 102.00 – 105.00% |
| Risk-free interest rate | 0.44 - 0.51% | 0.61 - 0.92% |
| Dividend yield | -% | -% |
| Expected term | 6.25 years | 5.13 – 6.25 years |



**10. Net loss per share**

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2021 | 2020 | 2021 |
| **Numerator:** | | | | |
| Net loss | $ (702) | $ (5,201) | $ (1,384) | $ (7,265) |
| **Denominator:** | | | | |
| Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted | 8,514,070 | 14,167,098 | 8,494,858 | 10,538,473 |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.08) | $ (0.37) | $ (0.16) | $ (0.69) |

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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2021 | 2020 | 2021 |
| Options to purchase common stock | 786,047 | 822,457 | 786,047 | 822,457 |
| Warrants to purchase common stock | - | 4,784,193 | - | 4,784,193 |
| Total | 786,047 | 5,606,650 | 786,047 | 5,606,650 |



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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this quarterly report and in our previously filed registration statement on Form S-1. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this quarterly report. See "Information Regarding Forward-Looking Statements." All amounts in this report are in U.S. dollars, unless otherwise noted.*

**Overview**

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

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

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

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

Since our formation we have devoted substantially all of our resources to developing our product candidates. We have incurred significant operating losses to date. Our net losses were $0.7 million, $1.4 million, $5.2 million and $7.3 million for the three and nine months ended September 30, 2020 and 2021, respectively. As of December 31, 2020 and September 30, 2021, we had an accumulated deficit of $5.9 million and $13.2 million, respectively. We expect that our operating expenses will increase significantly as we advance our product candidates through pre-clinical and clinical development, seek regulatory approval, and prepare for and, if approved, proceed to commercialization; acquire, discover, validate and develop additional product candidates; obtain, maintain, protect and enforce our intellectual property portfolio; and hire additional personnel. In addition, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company.

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

Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of our current product candidates and future product candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into agreements to raise capital as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our current product candidates and future product candidates. We plan to continue to use third-party service providers, including contract manufacturing organization, to carry out our pre-clinical and clinical development and to manufacture and supply the materials to be used during the development and commercialization of our product candidates.

**Recent Developments**

Between January 1, 2021 and May 19, 2021, we issued a series of convertible promissory notes in the aggregate principal amount of $1,098,000. These notes bear interest at a rate of 12% per annum and mature on the one year anniversary of their respective dates of issuance. These notes automatically converted into common stock upon consummation of our initial public offering at 70% of the public offering price per Unit.

As a result of its initial public offering ("IPO"), on July 13, 2021 the Company began trading on the Nasdaq Capital Market under the symbol "UNCY", and on July 15, 2021 received approximately $22,271,000 in net proceeds after deducting the underwriting discounts, commissions, and offering expenses.

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

**Renazorb Purchase Agreement**

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

Additionally, the Renazorb Purchase Agreement provides that until the earlier of (i) 36 months from the first date on which our stock trades on a public market, or (ii) the date upon which we attain a public market capitalization of $50,000,000 or greater, we are required to issue additional shares of our common stock as may be needed to ensure Spectrum maintains a 4% ownership of our issued and outstanding common stock on a fully-diluted basis. Fully-diluted shares of common stock for purposes of the Renazorb Purchase Agreement assumes conversion of any security convertible into or exchangeable or exercisable for common stock or any combination thereof, including any common stock reserved for issuance under a stock option plan, restricted stock plan, or other equity incentive plan approved by the Board of Directors of the Company immediately following the issuance of additional shares of our common stock (but prior to the issuance of any additional shares of common stock to Spectrum). 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 represents the final anti-dilution calculation required under the Spectrum Agreement, and no further anti-dilution shares will be issued. We are also required to pay Spectrum 40% of all of our sublicense income for any sublicense granted to certain sublicensees during the first 12 months after the Closing Date (as that term is defined in the Renazorb Purchase Agreement) and 20% of all other sublicense income. Our payment obligations to Spectrum will expire on the twentieth (20th) anniversary of the Closing Date of the Renazorb Purchase Agreement.



**Components of Results of Operations**

***Operating Expenses***

*Research and Development Expenses*

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

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

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

*General and Administrative Expenses*

General and administrative expenses consist principally of payroll and personnel expenses, including salaries and bonuses, benefits and stock-based compensation expenses, professional fees for legal, consulting, accounting and tax services, including information technology costs and utilities, and other general operating expenses not otherwise classified as research and development expenses, as well as services incurred pursuant to a services agreement with Globavir Biosciences Inc., a related party.

We anticipate that our general and administrative expenses will increase as a result of increased personnel costs, expanded infrastructure and higher consulting, legal and accounting services costs associated with complying with the applicable stock exchange and the SEC requirements, investor relations costs and director and officer insurance premiums associated with being a public company.

*Other Expenses*

Other expenses consist primarily of interest expense related to convertible notes and a loss on conversion of convertible notes.

**Results of Operations**

***Comparison of the Three Months Ended September 30, 2020 and 2021***

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

| | Three Months Ended September 30, |
|---|---|

| | 2020 | 2021 | Change | % Change |
|---|---|---|---|---|
| Operating expenses: | | | | |
| Research and development | $ 304 | $ 3,776 | $ 3,472 | 1,142% |
| General and administrative | 322 | 939 | 617 | 192% |
| Total operating expenses | 626 | 4,715 | 4,089 | 653% |
| Loss from operations | (626) | (4,715) | (4,089) | 653% |
| Other income (expenses): | | | | |
| Interest expense | (76) | (55) | 21 | (28)% |
| Loss on debt conversion | - | (431) | (431) | 100% |
| Total other income (expenses) | (76) | (486) | (410) | 540% |
| Net loss | $ (702) | $ (5,201) | $ (4,499) | 641% |



*Research and Development Expenses*

Research and development expenses increased by approximately $3,472,000, or 1,142%, from approximately $304,000 for the three months ended September 30, 2020 to approximately $3,776,000 for the three months ended September 30, 2021. The increase in research and development expenses was primarily due to a $2,191,000 increase in non-cash expense from the issuance of common stock pursuant to the anti-dilution clause in the purchase of in process research and development technology from Spectrum Pharmaceuticals, Inc. Non-cash stock compensation increased $111,000. In addition, development costs increased $766,000 due to product formulation and preclinical study services in the current period. New employee hires increased labor costs $374,000, and consulting and other costs increased $30,000 from the prior period.

*General and Administrative Expenses*

General and administrative expenses increased by $617,000, or 192%, from approximately $322,000 for the three months ended September 30, 2020 to approximately $939,000 for the three months ended September 30, 2021 primarily due to an increase of $342,000 in insurance expense for directors and officers. Labor costs increased $121,000 due to hiring of new employees. Consulting and professional services costs increased $79,000, and stock compensation, travel, and other costs increased $75,000.

*Other Income (Expenses)*

Other income (expenses) increased by $410,000, or 540% from approximately $76,000 for the three months ended September 30, 2020 to approximately $486,000 for the three months ended September 30, 2021. The increase was due primarily to the conversion to equity of our outstanding convertible notes as a result of our initial public offering which resulted in a non-cash loss on debt conversion of $431,000. The increase was partially offset by a decrease in interest expense of $21,000.

***Comparison of the Nine Months Ended September 30, 2020 and 2021***

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

| | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2020 | 2021 | Change | % Change |
| Operating expenses: | | | | |
| Research and development | $ 633 | $ 4,719 | $ 4,086 | 646% |
| General and administrative | 670 | 1,506 | 836 | 125% |
| Total operating expenses | 1,303 | 6,225 | 4,922 | 378% |
| Loss from operations | (1,303) | (6,225) | (4,922) | 378% |
| Other income (expenses): | | | | |
| Interest expense | (81) | (628) | (547) | 675% |
| Loss on debt conversion | - | (431) | (431) | 100% |
| Gain on extinguishment of debt | - | 19 | 19 | (100)% |
| Total other income (expenses) | (81) | (1,040) | (959) | 1,184% |
| Net loss | $ (1,384) | $ (7,265) | $ (5,881) | 425% |



*Research and Development Expenses*

Research and development expenses increased by approximately $4,086,000, or 646%, from approximately $633,000 for the nine months ended September 30, 2020 to approximately $4,719,000 for the nine months ended September 30, 2021. The increase in research and development expenses was primarily due to a $2,191,000 increase in non-cash expense from the issuance of common stock pursuant to the anti-dilution clause in the purchase of in process research and development technology from Spectrum Pharmaceuticals, Inc. Non-cash stock compensation costs increased $505,000. In addition, development costs increased $963,000 due to product formulation and preclinical study services in the current period. New employee hires increased labor costs $403,000, and consulting and other costs increased $24,000 from the prior period.

*General and Administrative Expenses*

General and administrative expenses increased by $836,000, or 125%, from approximately $670,000 for the nine months ended September 30, 2020 to approximately $1,506,000 for the nine months ended September 30, 2021 primarily due to an increase of $342,000 in insurance expense for directors and officers. Consulting and professional services costs increased $268,000. Labor costs increased $151,000 due to hiring of new employees. Stock compensation, travel, and other costs increased $75,000.

*Other Income (Expenses)*

Other income (expenses) increased by $959,000, or 1,184% from approximately $81,000 for the nine months ended September 30, 2020 to approximately $1,040,000 for the nine months ended September 30, 2021. The increase was due primarily to increased interest expense incurred on our convertible notes of $547,000 as well as conversion to equity of our outstanding convertible notes as a result of our initial public offering which resulted in a non-cash loss on debt conversion of $431,000. The increase was partially offset by a gain on extinguishment of our 2020 Paycheck Protection Plan loan of $19,000.

**Liquidity and Capital Resources**

***Sources of Liquidity***

Since our formation through September 30, 2021, we have funded our operations with the sale of common stock, convertible notes and from a loan from our Chief Executive Officer and principal stockholder. During 2020, we raised additional funds through private placements by issuing common stock for $141,000 and by issuing $1,290,000 in convertible notes to investors. During the nine months ended September 30, 2021, we raised $1,098,000 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 $22,271,000 in net proceeds after deducting the underwriting discounts, commissions and offering expenses. We intend to use the net proceeds from the IPO to complete pre-clinical and clinical studies, submit regulatory filings to the FDA, and for general and corporate purposes, including hiring additional management and conducting market research and other commercial planning.

***Future Funding Requirements***

We have incurred net losses since our inception. For the nine months ended September 30, 2021, we had a net loss of $7.3 million, and we expect to incur substantial additional losses in future periods. As of September 30, 2021, we had an accumulated deficit of $13.2 million.



We expect to continue incurring losses for the foreseeable future and will be required to raise additional capital in the future to complete our clinical trials, pursue product development initiatives and penetrate markets for the sale of our products. We believe that we will continue to have access to capital resources through possible equity offerings, debt financings, corporate collaborations or other means. There can be no assurance that we will be able to obtain additional financing on terms acceptable to us, on a timely basis or at all. If we are unable to secure additional capital, we may be required to curtail any clinical trials and development of new or existing products and take additional measures to reduce expenses in order to conserve our cash in amounts sufficient to sustain operations and meet our obligations. Based on the Company's current level of expenditures, after receiving the net proceeds received on July 15, 2021 as a result of the Company's IPO and given the Company's cash balance of approximately $18.0 million as of September 30, 2021, the Company believes that it has sufficient resources to continue operations for at least one year after the date that these financial statements are to be issued.

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

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

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



Adequate funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial

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

***Related Party Payable***

We entered into a Service Agreement on July 1, 2017, as amended on April 6, 2020 ("Service Agreement"), with Globavir Biosciences, Inc. ("Globavir"). Our Chief Executive Officer is also the Chief Executive Officer of Globavir. Pursuant to the Service Agreement, we receive administrative, consulting services, shared office space and other services in connection with our drug development program. The initial amended term of the Service Agreement expired on December 31, 2020, and the agreement shall automatically renew for successive one month periods after the initial termination date. Pursuant to the Service Agreement, we paid Globavir $50,000 per month through December 31, 2019 and $10,000 per month commencing on January 1, 2020. As of September 30, 2021, and December 31, 2020, respectively, $58,000 was prepaid to and $9,000 was payable to Globavir for service fees. Service fee expenses were $90,000 and $90,000 for the nine months ended September 30, 2021 and 2020, respectively, and were recorded as general and administrative expenses in the statements of operations.

***Convertible Notes***

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

We accounted for the 2021 Notes as stock-settled debt and we were accreting the carrying amount of the 2021 Notes to the settlement amount through maturity.

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

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



Interest expense, including discount accretion expense for the 2021 and 2020 Notes was $81,000 and $628,000 for the nine months ended September 30, 2020 and 2021, respectively.

As a result of our initial public offering on July 13, 2021, approximately $2,387,000 of principal and $191,000 of unpaid accrued interest related to the 2021 and 2020 Notes was converted into shares of common stock. The conversion resulted in a loss of $431,000 that is included as loss on debt conversion in the accompanying statements of operations for the three and nine months ended September 30, 2021.Interest expense was $81,000 and $628,000 for the nine months ended September 30, 2020 and 2021, respectively.

In 2017 and 2018, we raised $550,000 from the issuance of twelve convertible promissory notes (the "2018 Notes"). The 2018 Notes bear interest at 10% per annum which was payable at maturity. The 2018 Notes' principal and interest were due and payable on written demand by the majority of the 2018 Note holders on the two-year anniversary of the first 2018 Note issued. The first 2018 Note was issued on October 5, 2017 and, accordingly, all 2018 Notes would have matured on October 5, 2019. In the event we consummated an equity financing with an aggregate sales price of not less than $500,000, then the aggregate outstanding principal and unpaid interest would automatically convert into shares of common stock. The per-share price of the conversion would be equal to 75% of the price per share paid by the cash purchasers of the common stock sold in the financing. We accounted for the 2018 Notes as stock-settled debt and accreted the carrying amount of the 2018 Notes to the settlement amount through maturity. On July 31, 2019, all 2018 Notes principal and accrued interest were converted into 1,159,065 shares of common stock upon the consummation of a 2019 equity financing in excess of $500,000.

***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):

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2020** | **2021** |
| | **(unaudited)** | **(unaudited)** |
| Net cash (used in) provided by: | | |
| Operating activities | $ (921) | $ (4,364) |
| Financing activities | 969 | 22,375 |
| Net increase in cash | $ 48 | $ 18,011 |

*Cash Flows from Operating Activities*

Net cash used in operating activities was $4.4 million for the nine months ended September 30, 2021. Cash used in operating activities was primarily due to the use of funds for director and officer insurance premiums, development costs associated with our drug candidates, labor costs, consulting and accounting services, and other corporate expenditures for investor relations, compliance, and legal services. We incurred a net loss of $7.3 million after including the effect of non-cash adjustments for stock issuance, stock compensation, and a loss on the conversion of our convertible debt.

Net cash used in operating activities was $0.9 million for the nine months ended September 30, 2020. Cash used in operating activities resulted from a net loss of $1.4 million primarily driven by the use of funds in our operations to develop our product candidates as well as the deferral of the chief executive officer compensation of $0.3 million and an increase in accounts payable of $0.1 million.

*Cash Flows from Financing Activities*

Net cash provided by financing activities was $22.4 million for the nine months ended September 30, 2021 and was primarily related to proceeds received from our initial public offering, net of issuance and deferred offering costs. In addition, we issued convertible notes to investors for $1.1 million as well as the receipt of $0.1 million in proceeds from the exercise of options. Net repayments on loans from our chief executive officer offset the cash inflows by $1.1 million.

Net cash provided by financing activities was $1.0 million for the nine months ended September 30, 2020 and was primarily driven by proceeds received for convertible notes.

**Critical Accounting Policies, Significant Judgments and Use of Estimates**

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We consider our critical accounting policies and estimates to be related to research and development, stock-based compensation and common stock valuations. There have been no material changes to our critical accounting policies and estimates during the three months ended September 30, 2021 from those used for the year ended December 31, 2020. The below policies are listed to provide a list of our policies for the most significant critical policies.

**Research and Development**

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

**Stock-Based Compensation**

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



**Common Stock Valuations**

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

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

**JOBS Act Accounting Election**

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

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

Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of exemptions, including, without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

**Recent Accounting Pronouncements**

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

**Off-Balance Sheet Arrangements**

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

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not applicable.

**ITEM 4. CONTROLS AND PROCEDURES**

As of the end of the period covered by this Quarterly Report on Form 10-Q, 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 September 30, 2021.

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

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

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

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

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

We expect to complete the remediation by the end of 2022. We expect to incur additional costs to remediate this weakness, primarily personnel costs.

***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 third quarter ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, the internal control over financial reporting.



**PART II – OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

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 September 30, 2021 with respect to such matters.

**ITEM 1A. RISK FACTORS**

There have been no material changes from the risk factors disclosed in our Form 10-Q for the quarter ended June 30, 2021.

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

Not applicable

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

Not applicable.

**ITEM 6. EXHIBITS**

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

\+ Indicates a management contract or any compensatory plan, contract or arrangement.
\# Portions of this exhibit (indicated by asterisks) have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).



**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized on the 10th day of November, 2021.

| Signature | Title | Date |
|---|---|---|
| */s/ Shalabh Gupta*<br>Shalabh Gupta | Chief Executive Officer, President and Chairman<br>*(Principal Executive Officer)* | November 10, 2021 |
| */s/ John Townsend*<br>John Townsend | Chief Financial Officer<br>*(Principal Financial and Accounting Officer)* | November 10, 2021 |

**Exhibit 31.1**

**CERTIFICATION**

I, Shalabh Gupta, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Unicycive Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2021

*/s/ Shalabh Gupta*

Shalabh Gupta
Chief Executive Officer
(Principal Executive Officer)

**Exhibit 31.2**

**CERTIFICATION**

I, John Townsend, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Unicycive Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2021

*/s/ John Townsend*
John Townsend
Chief Financial Officer
(Principal Financial Officer)

**Exhibit 32.1**

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

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

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 10, 2021

*/s/ Shalabh Gupta*
Shalabh Gupta
Chief Executive Officer
(Principal Executive Officer)

**Exhibit 32.2**

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

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

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

November 10, 2021

*/s/ John Townsend*
John Townsend
Chief Financial Officer
(Principal Financial Officer)