# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended September 30, 2024**

**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: 001-40672**

# RANI THERAPEUTICS HOLDINGS, INC.

**(Exact Name of Registrant as Specified in its Charter)**

| **Delaware** | **86-3114789** |
|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **2051 Ringwood Avenue San Jose, California** | **95131** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (408) 457-3700**

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Class A common stock, par value $0.0001 per share | RANI | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 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, 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 Exchange Act). Yes ☐ No ☒

As of November 11, 2024, the registrant had 33,311,543 shares of Class A common stock, $0.0001 par value per share, outstanding, 23,977,139 shares of Class B common stock, $0.0001 par value per share, outstanding and no shares of Class C common stock, $0.0001 par value per share, outstanding. Certain holders of units of the registrant's consolidated subsidiary, Rani Therapeutics, LLC, who do not hold shares of the registrant's Class B common stock can exchange their units of Rani Therapeutics, LLC for 1,229,630 shares of the registrant's Class A common stock.

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*Unless otherwise stated or the context otherwise requires, the terms "we," "us," and "our," and similar references refer to Rani Therapeutics Holdings, Inc. ("Rani Holdings") and its consolidated subsidiary, Rani Therapeutics, LLC ("Rani LLC").*

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and consolidated financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, manufacturing costs, regulatory approvals, development and advancement of our oral delivery technology, timing and likelihood of success, potential partnering activities as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," "seek," "aim," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the progress and focus of our current and future clinical trials in the United States and abroad, and the reporting of data from those trials;
- our ability to advance product candidates into and successfully complete clinical trials;
- the beneficial characteristics, safety, efficacy, and therapeutic effects of our product candidates;
- our potential and ability to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
- our ability to complete development of the RaniPill HC or any redesign and conduct additional preclinical and clinical studies of the RaniPill HC or any future design of the RaniPill capsule to accommodate target payloads that are larger than the payload capacity of the RaniPill GO capsule used to date for clinical studies of our product candidates;
- our ability to further develop and expand our platform technology;
- our ability to utilize our technology platform to generate and advance additional product candidates;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- our financial performance;
- our ability to continue as a going concern;
- our plans relating to commercializing our product candidates, if approved;
- our ability to selectively enter into strategic partnership and the expected potential benefits thereof;
- the implementation of our strategic plans for our business and product candidates;
- our ability to continue to scale and optimize our manufacturing processes by expanding our use of automation;
- our estimates of the number of patients in the United States who suffer from the indications we target and the number of patients that will enroll in our clinical trials;
- the size of the market opportunity for our product candidates in each of the indications we target;
- our ability to continue to innovate and expand our intellectual property by developing novel formulations and new applications of the RaniPill capsule;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- the scope of protection we are able to establish and maintain for intellectual property rights, including our technology platform and product candidates;

- the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements;
- our ability to realize savings from any restructuring plans or cost-containment measures we propose to implement;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- our realization of any benefit from our organizational structure, taking into account our obligations under the Tax Receivable Agreement (defined herein) and the impact of any payments required to be made thereunder on our liquidity and financial condition; and
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act").

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions described in the section titled "Risk Factors" and elsewhere in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 20, 2024. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

**RANI THERAPEUTICS HOLDINGS, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(in thousands, except par value)**

| | September 30, 2024 (Unaudited) | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 4,277 | $ 5,864 |
| Marketable securities | 26,127 | 42,675 |
| Prepaid expenses and other current assets | 1,967 | 2,308 |
| Total current assets | 32,371 | 50,847 |
| Property and equipment, net | 5,496 | 6,105 |
| Operating lease right-of-use asset | 5,427 | 718 |
| Other assets | 246 | 246 |
| Total assets | $ 43,540 | $ 57,916 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,566 | $ 648 |
| Accrued expenses and other current liabilities | 1,867 | 1,726 |
| Deferred revenue | 600 | — |
| Current portion of long-term debt | 14,768 | 4,897 |
| Current portion of operating lease liability | 1,410 | 718 |
| Total current liabilities | 20,211 | 7,989 |
| Long-term debt, less current portion | 13,537 | 24,484 |
| Operating lease liability, less current portion | 4,017 | — |
| Total liabilities | 37,765 | 32,473 |
| Commitments and contingencies (Note 12) | | |
| Stockholders' equity: | | |
| Preferred stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of September 30, 2024 and December 31, 2023 | — | — |
| Class A common stock, $0.0001 par value - 800,000 shares authorized; 29,807 and 26,036 issued and outstanding as of September 30, 2024 and December 31, 2023, respectively | 3 | 3 |
| Class B common stock, $0.0001 par value - 40,000 shares authorized; 24,116 issued and outstanding as of September 30, 2024 and December 31, 2023 | 2 | 2 |
| Class C common stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of September 30, 2024 and December 31, 2023 | — | — |
| Additional paid-in capital | 97,067 | 85,762 |
| Accumulated other comprehensive gain (loss) | 8 | (12) |
| Accumulated deficit | (93,960) | (72,889) |
| Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc. | 3,120 | 12,866 |
| Non-controlling interest | 2,655 | 12,577 |
| Total stockholders' equity | 5,775 | 25,443 |
| Total liabilities and stockholders' equity | $ 43,540 | $ 57,916 |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**RANI THERAPEUTICS HOLDINGS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
**(in thousands, except per share amounts)**
**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Operating expenses | | | | |
| Research and development | $ 6,172 | $ 11,220 | $ 19,872 | $ 32,018 |
| General and administrative | 5,627 | 6,635 | 18,484 | 20,647 |
| Total operating expenses | $ 11,799 | $ 17,855 | $ 38,356 | $ 52,665 |
| Loss from operations | (11,799) | (17,855) | (38,356) | (52,665) |
| Other income (expense), net | | | | |
| Interest income and other, net | 414 | 839 | 1,403 | 2,626 |
| Interest expense and other, net | (1,337) | (1,316) | (3,909) | (3,789) |
| Net loss | $ (12,722) | $ (18,332) | $ (40,862) | $ (53,828) |
| Net loss attributable to non-controlling interest | (5,939) | (9,135) | (19,791) | (26,956) |
| Net loss attributable to Rani Therapeutics Holdings, Inc. | $ (6,783) | $ (9,197) | $ (21,071) | $ (26,872) |
| Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted | $ (0.24) | $ (0.36) | $ (0.78) | $ (1.06) |
| Weighted-average Class A common shares outstanding—basic and diluted | 28,836 | 25,552 | 27,071 | 25,380 |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**RANI THERAPEUTICS HOLDINGS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**
**(in thousands)**
**(Unaudited)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Net loss | $ (12,722) | $ (18,332) | $ (40,862) | $ (53,828) |
| Other comprehensive loss | | | | |
| Net unrealized gain on marketable securities | 24 | 45 | 37 | 64 |
| Comprehensive loss | $ (12,698) | $ (18,287) | $ (40,825) | $ (53,764) |
| Comprehensive loss attributable to non-controlling interest | (5,928) | (9,113) | (19,774) | (26,924) |
| Comprehensive loss attributable to Rani Therapeutics Holdings, Inc. | $ (6,770) | $ (9,174) | $ (21,051) | $ (26,840) |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**RANI THERAPEUTICS HOLDINGS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**
**(in thousands)**
**(Unaudited)**

| | Class A Common Stock | | Class B Common Stock | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Additional Paid In Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Non-Controlling Interest | Total Stockholders' Equity |
| Balance at December 31, 2023 | 26,036 | $ 3 | 24,116 | $ 2 | $ 85,762 | $ (12) | $ (72,889) | $ 12,577 | $ 25,443 |
| Issuance of common stock under employee equity plans | 175 | — | — | — | — | — | — | — | — |
| Effect of exchanges of non-corresponding Class A Units of Rani LLC | 83 | — | — | — | — | — | — | — | — |
| Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC | — | — | — | — | 45 | — | — | (45) | — |
| Stock-based compensation | — | — | — | — | 1,969 | — | — | 1,901 | 3,870 |
| Net loss | — | — | — | — | — | — | (7,483) | (7,296) | (14,779) |
| Other comprehensive gain | — | — | — | — | — | 1 | — | — | 1 |
| Balance at March 31, 2024 | 26,294 | $ 3 | 24,116 | $ 2 | $ 87,776 | $ (11) | $ (80,372) | $ 7,137 | $ 14,535 |
| Issuance of common stock under employee stock purchase plan, net of shares withheld for tax settlement | 110 | — | — | — | 221 | — | — | — | 221 |
| Issuance of common stock under employee equity plans, net of shares withheld for tax settlement | 85 | — | — | — | 14 | — | — | — | 14 |
| Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC | — | — | — | — | (108) | — | — | 108 | — |
| Stock-based compensation | — | — | — | — | 2,109 | — | — | 2,020 | 4,129 |
| Net loss | — | — | — | — | — | — | (6,805) | (6,556) | (13,361) |
| Other comprehensive gain | — | — | — | — | — | 6 | — | 6 | 12 |
| Balance at June 30, 2024 | 26,489 | $ 3 | 24,116 | $ 2 | $ 90,012 | $ (5) | $ (87,177) | $ 2,715 | $ 5,550 |
| Issuance of common stock in connection with the July Securities Purchase Agreement, net of issuance costs of $1,117 | 2,800 | — | — | — | 8,883 | — | — | — | 8,883 |
| Exercise of pre-funded warrants | 447 | — | — | — | — | — | — | — | — |
| Issuance of common stock under employee equity plans, net of shares withheld for tax settlement | 71 | — | — | — | (1) | — | — | — | (1) |
| Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC | — | — | — | — | (4,010) | — | — | 4,010 | — |
| Stock-based compensation | — | — | — | — | 2,183 | — | — | 1,858 | 4,041 |
| Net loss | — | — | — | — | — | — | (6,783) | (5,939) | (12,722) |
| Other comprehensive gain | — | — | — | — | — | 13 | — | 11 | 24 |
| Balance at September 30, 2024 | 29,807 | $ 3 | 24,116 | $ 2 | $ 97,067 | $ 8 | $ (93,960) | $ 2,655 | $ 5,775 |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**RANI THERAPEUTICS HOLDINGS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (CONTINUED)**
**(in thousands)**
**(Unaudited)**

| | Class A Common Stock | | Class B Common Stock | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Additional Paid In Capital | Accumulated Other Comprehensive Loss | Accumulated Deficit | Non-Controlling Interest | Total Stockholders' Equity |
| Balance at December 31, 2022 | 25,295 | $ 3 | 24,116 | $ 2 | $ 75,842 | $ (73) | $ (38,919) | $ 37,149 | $ 74,004 |
| Issuance of common stock under employee equity plans, net of shares withheld for tax settlement | 81 | — | — | — | (124) | — | — | — | (124) |
| Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC | — | — | — | — | 98 | — | — | (98) | — |
| Stock-based compensation | — | — | — | — | 2,202 | — | — | 2,213 | 4,415 |
| Net loss | — | — | — | — | — | — | (8,372) | (8,460) | (16,832) |
| Other comprehensive loss | — | — | — | — | — | 63 | — | 63 | 126 |
| Balance at March 31, 2023 | 25,376 | $ 3 | 24,116 | $ 2 | $ 78,018 | $ (10) | $ (47,291) | $ 30,867 | $ 61,589 |
| Issuance of common stock under employee stock purchase plan | 63 | — | — | — | 219 | — | — | — | 219 |
| Issuance of common stock under employee equity plans, net of shares withheld for tax settlement | 78 | — | — | — | (9) | — | — | — | (9) |
| Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC | — | — | — | — | (54) | — | — | 54 | — |
| Equity-based compensation | — | — | — | — | 2,572 | — | — | 2,569 | 5,141 |
| Net loss | — | — | — | — | — | — | (9,303) | (9,361) | (18,664) |
| Other comprehensive loss | — | — | — | — | — | (53) | — | (54) | (107) |
| Balance at June 30, 2023 | 25,517 | $ 3 | 24,116 | $ 2 | $ 80,746 | $ (63) | $ (56,594) | $ 24,075 | $ 48,169 |
| Issuance of common stock under employee equity plans, net of shares withheld for tax settlement | 319 | — | — | — | (29) | — | — | — | (29) |
| Effect of exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC | 42 | — | — | — | — | — | — | — | — |
| Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC | — | — | — | — | 159 | — | — | (159) | — |
| Forfeiture of restricted stock awards | (2) | — | — | — | (6) | — | — | (6) | (12) |
| Equity-based compensation | — | — | — | — | 2,510 | — | — | 2,468 | 4,978 |
| Net loss | — | — | — | — | — | — | (9,197) | (9,135) | (18,332) |
| Other comprehensive gain | — | — | — | — | — | 22 | — | 23 | 45 |
| Balance at September 30, 2023 | 25,876 | $ 3 | 24,116 | $ 2 | $ 83,380 | $ (41) | $ (65,791) | $ 17,266 | $ 34,819 |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**RANI THERAPEUTICS HOLDINGS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(in thousands)**
**(Unaudited)**

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2024** | **2023** |
| **Cash flows from operating activities** | | |
| Net loss | $ (40,862) | $ (53,828) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation expense | 12,040 | 14,522 |
| Depreciation and amortization | 762 | 595 |
| Non-cash operating lease expense | 1,332 | 780 |
| Amortization of debt discount and issuance costs | 174 | 174 |
| Net accretion and amortization of investments in marketable securities | (940) | (1,851) |
| Loss on disposal of property and equipment | 65 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 341 | (66) |
| Accounts payable | 918 | 68 |
| Accrued expenses and other current liabilities | 61 | 1,628 |
| Deferred revenue | 600 | — |
| Operating lease liabilities | (1,332) | (780) |
| Net cash used in operating activities | (26,841) | (38,758) |
| **Cash flows from investing activities** | | |
| Proceeds from maturities of marketable securities | 57,250 | 81,500 |
| Purchases of marketable securities | (39,725) | (63,852) |
| Purchases of property and equipment | (237) | (1,062) |
| Net cash provided by investing activities | 17,288 | 16,586 |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of common stock and pre-funded warrants in connection with the July Securities Purchase Agreement, net of issuance costs of $1,117 | 8,883 | — |
| Issuance of common stock under employee stock purchase plan | 221 | 219 |
| Proceeds from employee stock purchase plan | 99 | 80 |
| Exercise of options | 51 | — |
| Tax withholdings paid on behalf of employees for net share settlement | (38) | (162) |
| Repayment of debt | (1,250) | — |
| Net cash provided by financing activities | 7,966 | 137 |
| Net decrease in cash, cash equivalents and restricted cash equivalents | (1,587) | (22,035) |
| Cash, cash equivalents and restricted cash equivalents, beginning of period | 6,364 | 27,507 |
| Cash, cash equivalents and restricted cash equivalents, end of period | $ 4,777 | $ 5,472 |
| **Supplemental disclosures of non-cash investing and financing activities** | | |
| Right-of-use assets obtained in exchange for new operating lease liabilities | $ 4,731 | $ — |
| Remeasurement of operating lease right-of-use assets | $ 589 | $ 578 |
| Exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC | $ 298 | $ 169 |
| Interest income receivable included in prepaid expenses and other current assets | $ 29 | $ 188 |
| Property and equipment purchases included in accounts payable and accrued expenses and other current liabilities | $ — | $ 250 |

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

**1. Organization and Nature of Business**

***Description of Business***

Rani Therapeutics Holdings, Inc. ("Rani Holdings", and together with its consolidated subsidiary, the "Company") is a clinical-stage biotherapeutics company focusing on advancing technologies to enable the administration of biologics and drugs orally, to provide patients, physicians, and healthcare systems with a convenient alternative to painful injections. The Company's technology comprises a drug-agnostic oral delivery platform, the RaniPill capsule, which is designed to deliver a wide variety of drug substances, including antibodies, proteins, peptides, and oligonucleotides. The Company is advancing a portfolio of oral therapeutics using the RaniPill capsule. The Company is headquartered in San Jose, California and operates in one segment.

***Organization***

Rani Holdings was formed as a Delaware corporation in April 2021 for the purpose of facilitating an initial public offering ("IPO") of its Class A common stock. In connection with the IPO, the Company effected a series of organizational transactions (the "Organizational Transactions"), which, together with the IPO, were completed in August 2021, that resulted in the Company becoming the ultimate parent company of Rani Therapeutics, LLC ("Rani LLC"). The Company operates its business through Rani LLC.

As part of the Organizational Transactions, the Company entered into a Registration Rights Agreement with certain individuals and entities that continued to hold economic nonvoting Class A units of Rani LLC ("Class A Units"), collectively referred to herein as the "Continuing LLC Owners". The Continuing LLC Owners are entitled to exchange, subject to the terms of the Fifth Amended and Restated Limited Liability Company Agreement of Rani LLC (the "Rani LLC Agreement"), the Class A Units they hold in Rani LLC, together with the shares they hold of the Company Class B common stock (together referred to as a "Paired Interest"), in return for shares of the Company's Class A common stock on a one-for-one basis provided that, at the Company's election, the Company has the ability to effect a direct exchange of such Class A common stock or make a cash payment equal to a volume weighted average market price of one share of Class A common stock for each Paired Interest redeemed. Any shares of Class B common stock will be canceled on a one-for-one basis if, at the election of the Continuing LLC Owners, the Company redeems or exchanges such Paired Interest pursuant to the terms of the Rani LLC Agreement. As of September 30, 2024, certain individuals who continue to own interests in Rani LLC but do not hold shares of the Company's Class B common stock ("non-corresponding Class A Units") have the ability to exchange their non-corresponding Class A Units of Rani LLC for 1,261,690 shares of the Company's Class A common stock.

***Liquidity***

The Company has incurred recurring losses since its inception, including net losses of $40.9 million for the nine months ended September 30, 2024. As of September 30, 2024, the Company had an accumulated deficit of $94.0 million and for the nine months ended September 30, 2024, had negative cash flows from operations of $26.8 million. As of September 30, 2024, cash, cash equivalents and marketable securities totaled $30.4 million. Based on its available cash resources and current operating plan, there is substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date that its financial statements for the nine months ended September 30, 2024 are issued. The Company's existing capital resources, including the issuance and sale of Class A common stock and warrants pursuant to a securities purchase agreement with an institutional investor in July 2024, will not be sufficient to enable it to initiate any pivotal clinical trials. The Company will need to raise substantial additional funds in the future in order to complete the development of the RaniPill platform, to complete the clinical development of its product candidates and seek regulatory approval thereof, to expand its manufacturing capabilities, to further develop the RaniPill HC device and to commercialize any of its product candidates.

In July 2024, the Company entered into a securities purchase agreement (the "July Securities Purchase Agreement") with an institutional investor relating to the issuance and sale of: (i) 2,800,000 shares of Class A common stock, (ii) pre-funded warrants to purchase 446,753 shares of Class A common stock, (iii) Series A common warrants, which accompany the Class A common stock and pre-funded warrants, to purchase an aggregate of 3,246,753 shares of Class A common stock and (iv) Series B common warrants, which accompany the Class A common stock and pre-funded warrants, to purchase an aggregate of 3,246,753 shares of Class A common stock (the "July Offering"). The aggregate net proceeds from the July Offering totaled $8.9 million, after deducting placement agent fees and other offering expenses, and excluding potential proceeds, if any, from the exercise of the Series A common warrants and Series B common warrants issued in the July Offering. In August 2024, the pre-funded warrants were fully exercised for de minimis proceeds.

In August 2022, the Company entered into a Controlled Equity Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (collectively the "Agents"), pursuant to which the Company may offer and sell from time to time through the Agents up to $150 million of shares of its Class A common stock, in such share amounts as the Company may specify by notice to the Agents, in accordance with the terms and conditions set forth in the Sales Agreement. The potential proceeds from the Sales Agreement are expected to be used for general corporate purposes. As of September 30, 2024, the Company has no sales under the Sales Agreement.

The Company expects to continue to generate operating losses and negative operating cash flows for the foreseeable future as it continues to develop the RaniPill capsule. The Company expects to finance its future operations with its existing cash and through strategic financing opportunities that could include, but are not limited to, future offerings of its equity, such as “at the market offerings” as defined in Rule 415(a)(4) under the Securities Act, collaboration or licensing agreements, or the incurrence of debt. However, there is no guarantee that any of these strategic or financing opportunities will be executed or realized on favorable terms, if at all. As a result, the Company has concluded that management’s plans do not alleviate substantial doubt about the Company’s ability to continue as a going concern.

Subsequent to September 30, 2024, the Company completed an additional equity offering with the aggregate gross proceeds of approximately $10.0 million, before deducting placement agent fees and other estimated offering expenses payable by the Company, and excluding potential proceeds, if any, from the exercise of certain warrants issued in the offering (Note 16). The proceeds received do not alleviate substantial doubt about the Company’s ability to continue as a going concern.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

These condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). Certain prior period amounts have been reclassified to be consistent with current period presentation.

The Company operates and controls all of the business and affairs of Rani LLC and, through Rani LLC conducts its business. Because the Company manages and operates the business and controls the strategic decisions and day-to-day operations of Rani LLC and also has a substantial financial interest in Rani LLC, the Company consolidates the financial results of Rani LLC, and a portion of its net loss is allocated to the non-controlling interests in Rani LLC held by the Continuing LLC Owners. All intercompany accounts and transactions have been eliminated in consolidation.

***Unaudited Interim Condensed Consolidated Financial Statements***

The accompanying condensed consolidated financial statements have been prepared in accordance with U.S. GAAP for interim financial information and pursuant to Form 10-Q of Regulation S-X of the Securities and Exchange Commission (“SEC”). Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These unaudited condensed consolidated financial statements include all adjustments necessary to fairly state the financial position and the results of the Company's operations and cash flows for interim periods in accordance with U.S. GAAP. All such adjustments are of a normal, recurring nature. Operating results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024 or for any future period.

The consolidated balance sheet as of December 31, 2023 included herein was derived from the audited consolidated financial statements as of that date. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. Therefore, these interim condensed consolidated financial statements should be read in conjunction with the 2023 consolidated financial statements and notes included in the Company’s Annual Report on Form 10-K filed with the SEC on March 20, 2024.

***Use of Estimates***

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in the Company’s condensed consolidated financial statements and accompanying notes. The Company evaluates its estimates on an ongoing basis. The Company bases its estimates on its historical experience and also on assumptions that we believe are reasonable; however, actual results may differ materially and adversely from these estimates.

***Significant Accounting Policies***

A description of the Company's significant accounting policies is included in the audited consolidated financial statements within its Annual Report on Form 10-K for the year ended December 31, 2023. Except as noted below, there have been no material changes in the Company's significant accounting policies during the nine months ended September 30, 2024.

***Cash, Cash Equivalents and Restricted Cash Equivalents***

The following table provides a reconciliation of cash and cash equivalents and restricted cash equivalents reported as a component of prepaid expenses and other current assets on the condensed consolidated balance sheet which, in aggregate, represents the amount reported in the condensed consolidated statements of cash flows for the nine months ended September 30, 2024 and 2023:

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2024 | 2023 |
| End of Period: | | |
| Cash and cash equivalents | $ 4,277 | $ 4,972 |
| Restricted cash equivalents | 500 | 500 |
| Total cash, cash equivalents and restricted cash equivalents | $ 4,777 | $ 5,472 |

***Collaborative Arrangements***

The Company assesses whether its collaboration agreements are subject to ASC Topic 808: Collaborative Arrangements based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of Topic 808 and the Company concludes that its collaboration partner is not a customer, the Company presents amounts due from its collaboration partner as a reduction of research and development expense based on the nature of such payments.

***Revenue Recognition***

The Company primarily generates revenue from evaluation arrangements with certain pharmaceutical partners, under which the Company performs evaluation services of the partner's drug molecules using the RaniPill platform technology (Note 6).

Revenue is recognized when control of promised goods or services is transferred to a customer in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for its arrangements with customers, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The majority of the Company's contracts include only one performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is defined as the unit of account for revenue recognition. In determining whether performance obligations meet the criteria for being distinct, the Company considers a number of factors, such as the degree of interrelation and interdependence between obligations, and whether or not the good or service significantly modifies or transforms another good or service in the contract. Revenue for an individual contract is recognized at the related transaction price, which is the amount the Company expects to be entitled to in exchange for transferring the products and/or services. Revenue is recognized only to the extent that it is probable that a significant reversal of the cumulative amount recognized will not occur in future periods. As a practical expedient, we do not adjust the transaction price for the effects of a significant financing component if, at contract inception, the period between customer payment and the transfer of goods or services is expected to be one year or less. Variable consideration has not been material to our condensed consolidated financial statements.

Consistent with the Company's policies and practices as described above, the Company recognizes contract revenue from its evaluation arrangements using a cost-based input method, which most faithfully depicts the transfer of the performance obligation to the customer. Accordingly, the Company will recognize contract revenue based on actual costs incurred as a percentage of total estimated costs the Company expects to incur to deliver its performance obligation. These actual costs consist of the internal labor efforts, in vivo testing services and materials costs related to the agreement, as the costs incurred over time will reflect the transfer of its performance obligations to the customer. The cumulative effect of revisions to estimated costs to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts are reasonably estimable. Such costs are expensed when incurred and are included as a component of research and development expenses in the Company's condensed consolidated statements of operations and comprehensive loss.

Customer options, such as options granted to allow a customer to acquire later stage evaluation services, are evaluated at contract inception in order to determine whether those options provide a material right (i.e., an optional good or service offered for free or at a discount) to the customer. If the customer options represent a material right, the material right is treated as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the standalone selling price, and revenue is recognized when or as the future goods or services are transferred or when the option expires. Customer options that are not material rights do not give rise to a separate performance obligation, and as such, the additional consideration that would result from a customer exercising an option in the future is not included in the transaction price for the current contract. Instead, the option is deemed a marketing offer, and additional option fee payments are recognized or being recognized as revenue when the licensee exercises the option. The exercise of an option that does not represent a material right is treated as a separate contract for accounting purposes.

Incremental costs of obtaining contracts are expensed when incurred when the amortization period of the assets that otherwise would have been recognized is one year or less. To date, none of these costs have been material. The costs to fulfill the contracts are determined to be immaterial and are recognized as an expense when incurred.

Contract assets are generated when contractual billing schedules differ from revenue recognition timing and the Company records a contract receivable when it has an unconditional right to consideration. No contract assets balance was recorded as of September 30, 2024 or December 31, 2023.

Contract liabilities are recorded as deferred revenue when cash payments are received or due in advance of performance or where the Company has unsatisfied performance obligations. As of September 30, 2024, the Company had deferred revenue of $0.6 million related to unsatisfied evaluation services (Note 6). There was no deferred revenue as of December 31, 2023.

***Recently Issued Accounting Pronouncements***

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures (“ASU 2023-07”). The amendments in ASU 2023-07 are intended to improve reportable segment disclosure, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for annual periods beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The amendments in this ASU should be applied retrospectively to all prior periods presented in the financial statements. Early adoption is permitted. The Company is evaluating the impact of this guidance on its condensed consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures (“ASU 2023-09”). ASU 2023-09 requires enhanced annual disclosures regarding the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 and may be adopted on a prospective or retrospective basis. Early adoption is permitted. The Company is evaluating the impact of this guidance on its condensed consolidated financial statements and related disclosures.

**3. Cash Equivalents, Restricted Cash Equivalents and Marketable Securities**

The following tables summarizes the amortized cost and fair value of the Company's cash equivalents, restricted cash equivalents and marketable securities by major investment category (in thousands):

| | As of September 30, 2024 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | Estimated Fair Value |
| Current assets: | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 2,090 | $ — | $ — | $ 2,090 |
| Total cash equivalents | 2,090 | — | — | 2,090 |
| Restricted cash equivalents: | | | | |
| Money market funds | 500 | — | — | 500 |
| Total cash equivalents and restricted cash equivalents | 2,590 | — | — | 2,590 |
| Marketable securities: | | | | |
| U.S. Treasuries and agencies | 26,118 | 9 | — | 26,127 |
| Total cash equivalents, restricted cash equivalents and marketable securities | $ 28,708 | $ 9 | $ — | $ 28,717 |

| | As of December 31, 2023 | | | |
|---|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Unrealized Losses | Estimated Fair Value |
| Current assets: | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 3,339 | $ — | $ — | $ 3,339 |
| Total cash and cash equivalents | 3,339 | — | — | 3,339 |
| Restricted cash equivalents: | | | | |
| Money market funds | 500 | — | — | 500 |
| Total cash equivalents and restricted cash equivalents | 3,839 | — | — | 3,839 |
| Marketable securities: | | | | |
| U.S. Treasuries and agencies | 35,513 | — | (18) | 35,495 |
| Corporate debt securities | 1,971 | — | (8) | 1,963 |
| Commercial paper | 5,219 | — | (2) | 5,217 |
| Total marketable securities | 42,703 | — | (28) | 42,675 |
| Total cash equivalents, restricted cash equivalents and marketable securities | $ 46,542 | $ — | $ (28) | $ 46,514 |

All marketable securities are classified as short-term. The Company regularly reviews its available-for-sale marketable securities in an unrealized loss position and evaluates the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. As of September 30, 2024, the aggregate difference between the amortized cost and fair value of each security in an unrealized loss position was de minimis. Since any provision for expected credit losses for a security held is limited to the amount the fair value is less than its amortized cost, no allowance for expected credit loss was deemed necessary at September 30, 2024. As of September 30, 2024 and December 31, 2023, interest income receivable recorded as a component of prepaid expenses and other current assets on the condensed consolidated balance sheet was de minimis and $0.2 million, respectively.

**4. Fair Value Measurements**

The following tables detail information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of inputs used in such measurements (in thousands):

| | As of September 30, 2024 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 2,090 | $ — | $ — | $ 2,090 |
| Restricted cash equivalents: | | | | |
| Money market funds | 500 | — | — | 500 |
| Marketable securities | | | | |
| U.S. Treasuries and agencies | 26,127 | — | — | 26,127 |
| Total assets | $ 28,717 | $ — | $ — | $ 28,717 |

| | As of December 31, 2023 | | | |
|---|---|---|---|---|
| | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Cash equivalents: | | | | |
| Money market funds | $ 3,339 | $ — | $ — | $ 3,339 |
| Restricted cash equivalents: | | | | |
| Money market funds | 500 | — | — | 500 |
| Marketable securities | | | | |
| U.S. Treasuries and agencies | 35,495 | — | — | 35,495 |
| Corporate debt securities | — | 1,963 | — | 1,963 |
| Commercial paper | — | 5,217 | — | 5,217 |
| Total assets | $ 39,334 | $ 7,180 | $ — | $ 46,514 |

Level 1 and Level 2 financial instruments are comprised of investments in money market funds and fixed-income securities. The Company estimates the fair value of its Level 2 financial instruments by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

There were no transfers between Level 1, Level 2 and Level 3 of the fair value hierarchy for any of the periods presented.

**5. Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consist of the following (in thousands):

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Accrued interest | $ 823 | $ 500 |
| Payroll and related costs | 324 | 313 |
| Accrued rent | 317 | — |
| Accrued professional fees | 190 | 235 |
| Accrued preclinical and clinical trial costs | 30 | 424 |
| Other | 183 | 254 |
| Total accrued expenses and other current liabilities | $ 1,867 | $ 1,726 |

**6. Collaborative and Evaluation Arrangements**

***ProGen Co., Ltd.***

In June 2024, the Company and ProGen Co., Ltd. ("ProGen") entered into a Collaboration Agreement (the "Collaboration Agreement"). Under the Collaboration Agreement, the Company and ProGen will collaborate to manufacture, develop, seek regulatory approvals for and, if approved, commercialize a product (the "Product") combining ProGen's GLP-1/GLP-2 dual agonist compound, PG-102, and the RaniPill HC oral delivery device (the "Device") in the field of weight management (including without limitation obesity, weight reduction and weight maintenance) in humans (the "Collaboration").

Under the Collaboration Agreement, development costs, as well as operating profits and losses from the commercialization of the Product, will be equally shared by the Company and ProGen. The Company and ProGen each granted to the other party an exclusive right and license (except with respect to the other party's affiliates and sublicensees) to certain intellectual property to develop the Product for weight management and an exclusive right and license to seek regulatory approval for, and to use, sell, offer to sell, import and commercialize the Product in their assigned territories. The Company will lead the development of the Product in the United States, Canada, Europe (including the United Kingdom) and Australia, and ProGen will lead development in all other countries.

Each party has the right to opt-out of the Collaboration ("Opt-Out") at any time upon prior written notice to the other party. Following an Opt-Out, the continuing party shall have sole right to develop, conduct regulatory activities for and commercialize the Product on a worldwide basis. The Opt-Out party shall share all development costs and operating profit (or loss) through the effective date of the Opt-Out, and all costs to complete the conduct of any clinical trials of Product that have been initiated prior to delivery of the Opt-Out notice, even if the costs are incurred or the trials are completed after the effective date of the Opt-Out. The continuing party shall pay to the Opt-Out party low single to mid-single digit royalties on net sales of the Product made after the Opt-Out date depending on when the Opt-Out occurs.

The Company determined that the Collaboration Agreement is not a contract with a customer and is therefore accounted for under ASC Topic 808. The Company evaluates the presentation of amounts due from ProGen based on the nature of each separate activity. Reimbursements from ProGen are recognized as contra-research and development expense on the Consolidated Statement of Operations once earned and collectability is assured. As of September 30, 2024, no reimbursement has been received from or billed by ProGen nor recorded as contra-research and development expense.

***Evaluation Arrangement***

In August 2024, the Company entered into a contract to conduct evaluation services of certain customer compounds for oral delivery using the RaniPill HC. This customer paid the Company an up-front payment of $0.6 million upon execution of the contract. Upon completion of the evaluation services, the Company is entitled to a final $0.6 million payment for an aggregate total of $1.2 million due under the contract. In addition, if agreed upon, the agreement allows for joint filing of certain intellectual property protection in which all associated expenses will be shared equally. The customer has the ability to terminate the agreement at any time by providing 10 days' written notice after the effective date of the contract. The contract can be terminated for cause by either party based on uncured material breach by the other party. Upon early termination, all ongoing activities under the agreement and all mutual collaboration, development and commercialization licenses and sublicenses will terminate.

The Company identified one material promise under the contract, the obligation to perform services to evaluate if the customers compounds can be orally delivered using the RaniPill HC, which was concluded to be a single performance obligation. For revenue recognition purposes, the Company determined that the duration of the contract began on the effective date in August 2024 and will end the sooner of the contractual 1-year term or upon the completion of the evaluation services. The contract duration is defined as the period in which parties to the contract have present enforceable rights and obligations. For the nine months ended September 30, 2024, no contract revenue was recognized for evaluation services performed. As of September 30, 2024, the Company had deferred revenue of $0.6 million related to unsatisfied evaluation services. There was no deferred revenue as of December 31, 2023.

**7. Related Party Transactions**

InCube Labs, LLC (“ICL”) is wholly-owned by the Company’s founder and Chairman and his family. The founder and Chairman is the father of the Company’s Chief Executive Officer. The Company’s Chief Scientific Officer is also the brother of the founder and Chairman and thus uncle of the Company’s Chief Executive Officer.

***Service Agreements***

In June 2021, Rani LLC entered into a service agreement with ICL effective retrospectively to January 1, 2021, and subsequently amended such agreement in March 2022 (as amended, the "Rani LLC-ICL Service Agreement"), pursuant to which Rani LLC and ICL agreed to provide personnel services to the other upon requests. Under the amendment in March 2022, Rani LLC has a right to occupy certain facilities leased by ICL in Milpitas, California and San Antonio, Texas (“Occupancy Services”) for general office, research and development, and light manufacturing. The Rani LLC-ICL Service Agreement has a twelve-month term and will automatically renew for successive twelve-month periods unless terminated; except that the Occupancy Services in Milpitas, California had a term until February 2024, following an extension granted in July 2022, and the Occupancy Services in San Antonio, Texas continue until either party gives six months’ notice of termination. Except for the Occupancy Services, Rani LLC or ICL may terminate services under the Rani LLC-ICL Service Agreement upon 60 days' notice to the other party. The Rani LLC-ICL Service Agreement specifies the scope of services to be provided as well as the methods for determining the costs of services. Costs are billed or charged on a monthly basis by ICL or Rani LLC, respectively. In December 2023, Rani LLC provided to ICL notice of termination of the Occupancy Services in San Antonio, which took effect in June 2024. In March 2024, the Company extended the Occupancy Services for the facility in Milpitas, California for an additional six-month term through August 2024 and increased the payment for such Occupancy Services during the extension period. The Occupancy Services for the facility in Milpitas, California expired in August 2024.

In June 2021, Rani Management Services, Inc. (“RMS”) entered into a service agreement with ICL effective retrospectively to January 1, 2021, pursuant to which ICL agreed to rent a specified portion of its facility in San Jose, California to RMS. Additionally, RMS and ICL agreed to provide personnel services to the other upon requests based on rates specified in the agreement. In April 2022, RMS assigned the agreement to Rani LLC. In December 2022, RMS was dissolved. In March 2024, the Company entered into an amendment to increase the Occupancy Services from 23,000 square feet to 24,000 square feet (such agreement, as assigned and amended, the “RMS-ICL Service Agreement”). The RMS-ICL Service Agreement has a twelve-month term and will automatically renew for successive twelve-month periods unless terminated. Rani LLC or ICL may terminate services under the RMS-ICL Service Agreement upon 60 days' notice to the other party, except for occupancy which requires six months’ notice. The RMS-ICL Service Agreement specifies the scope of services to be provided as well as the methods for determining the costs of services. Costs are billed or charged on a monthly basis by ICL or Rani LLC, respectively, as well as allocations of expenses based upon Rani LLC’s utilization of ICL’s facilities and equipment.

The table below details the amounts charged by ICL for services and rent, net of the amount that the Company charged ICL, which is included in the condensed consolidated statements of operations (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| Research and development | $ 201 | $ 280 | $ 768 | $ 889 |
| General and administrative | 41 | 87 | 187 | 220 |
| Total | $ 242 | $ 367 | $ 955 | $ 1,109 |

As of September 30, 2024, one of the Company's facilities was owned by an entity affiliated with the Company’s Chairman (Note 8). The Company pays for the use of this facility through the RMS-ICL Service Agreement.

***Exclusive License, Intellectual Property and Common Unit Purchase Agreement***

In June 2021, ICL and the Company, through Rani LLC, entered into an Amended and Restated Exclusive License Agreement which replaced the 2012 Exclusive License Agreement between ICL and Rani LLC, as amended in 2013, and terminated the 2012 Intellectual Property Agreement between ICL and Rani LLC, as amended in June 2013. Under the Amended and Restated Exclusive License Agreement, the Company has a fully paid, exclusive license under certain scheduled patents related to optional features of the device and certain other scheduled patents to exploit products covered by those patents in the field of oral delivery of sensors, small molecule drugs or biologic drugs including, any peptide, antibody, protein, cell therapy, gene therapy or vaccine. The Company covers patent-related expenses and, after a certain period, the Company will have the right to acquire four specified United States patent families from ICL by making a one-time payment of $0.3 million to ICL for each United States patent family that the Company desires to acquire, up to $1.0 million in the aggregate. This payment will not become an obligation until the fifth anniversary of the Amended and Restated Exclusive License Agreement. The Amended and Restated Exclusive License Agreement will terminate when there are no remaining valid claims of the patents licensed under the Amended and Restated Exclusive License Agreement. Additionally, the Company may terminate the Amended and Restated Exclusive License Agreement in its entirety or as to any particular licensed patent upon notification to ICL of such intent to terminate.

***Non-Exclusive License Agreement between Rani and ICL ("Non-Exclusive License Agreement")***

In June 2021, the Company, through Rani LLC, entered into the Non-Exclusive License Agreement with ICL a related party, pursuant to which the Company granted ICL a non-exclusive, fully-paid license under specified patents that were assigned from ICL to the Company. Additionally, the Company agreed not to license these patents to a third party in a specific field outside the field of oral delivery of sensors, small molecule drugs or biologic drugs including, any peptide, antibody, protein, cell therapy, gene therapy or vaccine, if ICL can prove that it or its sublicensee has been in active development of a product covered by such patents in that specific field. ICL may grant sublicenses under this license to third parties only with the Company's prior approval. The Non-Exclusive License Agreement will continue in perpetuity unless earlier terminated.

***Intellectual Property Agreement with Mir Imran (the "Mir Agreement")***

In June 2021, the Company, through Rani LLC, entered into the Mir Agreement, pursuant to which the Company and Mir Imran agreed that the Company would own all intellectual property conceived (i) using any of the Company's people, equipment, or facilities or (ii) that is within the field of oral delivery of sensors, small molecule drugs or biologic drugs including, any peptide, antibody, protein, cell therapy, gene therapy or vaccine. Neither the Company nor Mir Imran may assign the Mir Agreement to any third party without the prior written consent of the other party. The initial term of the Mir Agreement was three years, which could be extended upon mutual consent of the parties. In June 2024, the parties agreed to extend the term of the Mir Agreement by ninety (90) days. The Mir Agreement expired in September 2024. Expiration of the Mir Agreement does not affect the assignment to, and ownership by, the Company of intellectual property conceived during the term of the Mir Agreement.

***Tax Receivable Agreement***

Certain parties to the tax receivable agreement ("TRA"), entered into in August 2021 pursuant to the IPO and Organizational Transactions are related parties of the Company. The TRA provides that the Company pay to ICL and the other Continuing LLC Owners 85% of the amount of tax benefits, if any, it is deemed to realize from exchanges of Paired Interests. During each of the nine months ended September 30, 2024 and 2023, these parties to the TRA exchanged zero Paired Interests that resulted in tax benefits subject to the TRA.

***Registration Rights Agreement***

In connection with the IPO, the Company entered into a Registration Rights Agreement. ICL and its affiliates are parties to this agreement. The Registration Rights Agreement provides certain registration rights whereby, at any time following the IPO and the expiration of any related lock-up period, ICL and its affiliates can require the Company to register under the Securities Act of 1933, as amended (the "Securities Act") shares of Class A common stock issuable to ICL and its affiliates upon, at the Company's election, redemption or exchange of their Paired Interests. The Registration Rights Agreement also provides for piggyback registration rights. In March 2022, certain holders of the Company's Class A common stock considered to be related parties were made parties to the Registration Rights Agreement. As a result of certain stockholders exercising their registration rights under the Registration Rights Agreement, in December 2022, the Company filed a registration statement on Form S-3 to register 6,009,542 shares of Class A common stock of the Company held by certain of its stockholders.

***Rani LLC Agreement***

The Company operates its business through Rani LLC. In connection with the IPO, the Company and the Continuing LLC Owners, including ICL and its affiliates, entered into the Rani LLC Agreement. The governance of Rani LLC, and the rights and obligations of the holders of LLC Interests, are set forth in the Rani LLC Agreement. As Continuing LLC Owners, ICL and its affiliates are entitled to exchange, subject to the terms of the Rani LLC Agreement, Paired Interests for Class A common stock of the Company; provided that, at the Company's election, the Company may effect a direct exchange of such Class A common stock or make a cash payment equal to a volume weighted average market price of one share of Class A common stock for each Paired Interest redeemed.

During each of the nine months ended September 30, 2024 and 2023, certain related parties that are party to the Rani LLC Agreement exchanged zero Paired Interests for an equal number of shares of the Company's Class A common stock.

**8. Leases**

In November 2023, Rani LLC and BKM South Bay 240, LLC ("Landlord") entered into the Standard Industrial/Commercial Multi-Tenant Lease - Net (the "Lease"). Pursuant to the terms of the Lease, Rani LLC is leasing approximately 33,000 square feet of space in Fremont, California, which is part of a two-building project (the "Project"). The initial term of the Lease commenced in February 2024, and the duration of the initial term is 63 months. Subject to certain conditions, Rani LLC has an option to renew the Lease for one additional 5-year term at the then-prevailing market rate. The monthly base rent for the initial term of the Lease is approximately $95,000 per month, subject to a 4% increase each year. Rani LLC is also responsible for the payment of additional rent to cover its share of common area operating expenses, including taxes, insurance, utilities, and repair and maintenance of the premises and common areas of the Project.

The Company pays for the use of its office, laboratory and manufacturing facility in San Jose, California as part of the RMS-ICL Service Agreement. In April 2022, RMS assigned the RMS-ICL Service Agreement to Rani LLC. In December 2022, RMS was dissolved. In March 2024, the Company entered into an amendment to increase the Occupancy Services from 23,000 square feet to 24,000 square feet. The RMS-ICL Service Agreement has a twelve-month term and will automatically renew for successive twelve-month periods unless Rani LLC or ICL terminate occupancy under the RMS-ICL Service Agreement upon six months' notice. In January 2024, the Company determined it to be reasonably certain that it would exercise its renewal option for a successive twelve-month period through 2025. The Company accounted for the renewal option as a lease modification that did not result in a separate contract and recognized the additional right-of-use asset and corresponding lease liabilities associated with the Rani LLC-ICL Service Agreement in its condensed consolidated balance sheet.

Under the Rani LLC-ICL Service Agreement amended in March 2022, Rani LLC had a right to occupy certain facilities leased by ICL in Milpitas, California and San Antonio, Texas for general office, research and development, and light manufacturing. The Rani LLC-ICL Service Agreement has a twelve-month term and will automatically renew for a successive twelve-month periods unless terminated; except that the Occupancy Services in Milpitas, California had a term until February 2024, following an extension granted in July 2022. The Company accounted for the lease extension as a lease modification that did not result in a separate contract and recognized the right-of-use asset and lease liabilities associated with the Rani LLC-ICL Service Agreement in the consolidated balance sheet as of the modification date in July 2022. In December 2023, the Company provided to ICL notice of termination of the Occupancy Services in San Antonio, which took effect in June 2024. In March 2024, the Company extended the Occupancy Services for the facility in Milpitas, California for an additional six-month term through August 2024 and increased the payment for such Occupancy Services during the extension period. The Occupancy Services for the facility in Milpitas, California expired in August 2024.

The Company's leases are accounted for as operating leases and require certain fixed payments of real estate taxes and insurance in addition to future minimum lease payments, and certain variable payments of common area maintenance costs and building utilities. Variable lease payments are expensed in the period in which the obligation for those payments is incurred. These variable lease costs are payments that vary in amount beyond the commencement date, for reasons other than passage of time. Variable lease payments are excluded in the total operating lease expense and immaterial for the periods presented.

Supplemental information on the Company's condensed consolidated balance sheet and statements of cash flows as of September 30, 2024 and 2023 and for the nine months ended September 30, 2024 and 2023, respectively, related to the Company's leases was as follows (in thousands):

| | September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Weighted-average remaining lease term (in years) | 4.1 | 1.1 |
| Weighted-average discount rate | 10.4% | 10.4% |

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Cash paid for amounts included in lease liabilities: | | |
| Operating cash flows used for operating leases | $ 1,015 | $ 780 |

As of September 30, 2024, minimum annual rental payments under the Company's operating lease agreements are as follows (in thousands), excluding short-term leases:

| | |
|---|---|
| Year ending December 31, | |
| 2024 (remaining three months) | $ 465 |
| 2025 | 1,902 |
| 2026 | 1,229 |
| 2027 | 1,278 |
| 2028 | 1,330 |
| 2029 | 458 |
| Total undiscounted future minimum lease payments | $ 6,662 |
| Less: Imputed interest | (1,235) |
| Total operating lease liability | $ 5,427 |
| Less: Current portion of operating lease liability | 1,410 |
| Operating lease liability, net current portion | $ 4,017 |

**9. Warrants**

In July 2024, as part of the July Offering, the Company issued (i) pre-funded warrants to purchase 446,753 shares of Class A common stock, (ii) Series A common warrants to purchase an aggregate of 3,246,753 shares of Class A common stock and (iii) Series B common warrants to purchase an aggregate of 3,246,753 shares of Class A common stock. The pre-funded warrants are exercisable immediately and have an unlimited term and an exercise price of $0.0001 per share. The Series A Warrants will be exercisable following the six-month anniversary of the closing date of the July Offering, will expire 18 months following the date of issuance and will have an exercise price of $3.08 per share. The Series B warrants will be exercisable following the six-month anniversary of the closing date of the July Offering, will expire five and a half years from the date of issuance and will have an exercise price of $3.08 per share. The Series A warrants and Series B warrants include certain rights upon "fundamental transactions," as described in the Series A warrants and Series B warrants, including in the Series B warrants the right of the holders thereof to receive from the Company or a successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of Class A common stock in such fundamental transaction in the amount of the Black Scholes value (as described in the Series B warrants) of the unexercised portion of the applicable Series B warrants on the date of the consummation of the fundamental transactions. In August 2024, the pre-funded warrants were fully exercised for de minimis proceeds. As of September 30, 2024, there were 3,246,753 Series A warrants and 3,246,753 Series B warrants outstanding. Subsequent to September 30, 2024, the Series A warrants were canceled (Note 16).

In August 2022, in conjunction with a loan and security agreement (Note 13), the Company issued warrants to purchase 76,336 shares of the Company's Class A common stock. The warrants are exercisable for a period of five years from the grant date, as may be adjusted for certain anti-dilution adjustments, dividends, stock splits, and reverse stock splits, at an exercise price per share equal to $11.79, which may be net share settled at the option of the holder. As of September 30, 2024, there were 76,336 warrants outstanding.

**10. Stockholders' Equity**

As of September 30, 2024, Rani Holdings held approximately 54% of the Class A Units of Rani LLC, and approximately 46% of the outstanding Class A Units of Rani LLC are held by the Continuing LLC Owners. From the date of the Organizational Transactions to September 30, 2024, 5,173,947 Paired Interests and 283,832 non-corresponding Class A Units of Rani LLC were exchanged for an equal number of shares of the Company's Class A common stock. For each of the nine months ended September 30, 2024 and 2023, certain of the Continuing LLC Owners executed an exchange of zero Paired Interests and 83,377 and zero non-corresponding Class A Units of Rani LLC, respectively, in return for an equal number of shares of the Company's Class A common stock. The corresponding shares of the Company's Class B common stock included in the exchange of Paired Interests were subsequently canceled and retired pursuant to the terms of the Rani LLC Agreement. In accordance with the Rani LLC Agreement, Rani LLC also issues a corresponding Class A Unit to Rani Holdings for each share of common stock issued by Rani Holdings. This increases Rani Holdings' ownership in Rani LLC.

In July 2024, the Company closed the July Offering, pursuant to which it issued and sold: (i) 2,800,000 shares of Class A common stock, (ii) pre-funded warrants to purchase 446,753 shares of Class A common stock, (iii) Series A common warrants, which accompany the Class A common stock and pre-funded warrants, to purchase an aggregate of 3,246,753 shares of Class A common stock and (iv) Series B common warrants, which accompany the Class A common stock and pre-funded warrants, to purchase an aggregate of 3,246,753 shares of Class A common stock. The aggregate net proceeds from the July Offering totaled $8.9 million, after deducting placement agent fees and other offering expenses, and excluding potential proceeds, if any, from the exercise of the Series A common warrants and Series B common warrants issued in the July Offering. In August 2024, the pre-funded warrants were fully exercised for de minimis proceeds.

In August 2022, the Company entered into the Sales Agreement with the Agents, pursuant to which the Company may offer and sell from time to time through the Agents up to $150.0 million of shares of its Class A common stock, in such share amounts as the Company may specify by notice to the Agents, in accordance with the terms and conditions set forth in the Sales Agreement. The potential proceeds from the Sales Agreement are expected to be used for general corporate purposes. As of September 30, 2024, the Company had no sales under the Sales Agreement.

**11. Stock-Based Compensation**

***Stock Options***

A summary of stock option activity during the periods indicated is as follows:

| | Number of Stock Option Awards | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Balance at December 31, 2023 | 6,639,811 | $ 6.37 | 8.48 | $ 13,377 |
| Granted | 4,154,325 | $ 3.74 | 9.49 | $ — |
| Exercised | (18,757) | $ 2.72 | | |
| Canceled | (478,961) | $ 5.36 | | |
| Balance at September 30, 2024 | 10,296,418 | $ 5.36 | 8.35 | $ 25 |
| Exercisable at September 30, 2024 | 4,713,481 | $ 7.62 | 7.66 | $ — |
| Nonvested at September 30, 2024 | 5,582,937 | $ 3.46 | 8.99 | $ 25 |

As of September 30, 2024, there was $21.8 million of unrecognized stock-based compensation expense related to stock options which is expected to be recognized over a weighted-average period of approximately 2.8 years.

***Restricted Stock Units***

A summary of restricted stock unit ("RSU") activity during the periods indicated is as follows:

| | Number of Restricted Stock Units | Weighted Average Grant-Date Fair Value per Share |
|---|---|---|
| Balance at December 31, 2023 | 1,276,111 | $ 7.16 |
| Vested | (323,611) | $ 7.69 |
| Forfeited | (59,206) | $ 7.37 |
| Balance at September 30, 2024 | 893,294 | $ 6.96 |

As of September 30, 2024, there was $5.6 million of unrecognized stock-based compensation expense related to RSUs which is expected to be recognized over a weighted-average period of approximately 2.3 years. The total fair value of RSUs vested was $1.0 million for the nine months ended September 30, 2024.

***Restricted Stock Awards***

A summary of restricted stock award ("RSA") activity during the periods indicated is as follows:

| | Number of Restricted Stock Awards | Weighted Average Grant-Date Fair Value per Share |
|---|---|---|
| Balance at December 31, 2023 | 33,586 | $ 6.15 |
| Vested | (22,616) | $ 6.14 |
| Forfeited | (218) | $ 6.13 |
| Balance at September 30, 2024 | 10,752 | $ 6.15 |

As of September 30, 2024, unrecognized stock-based compensation expense related to RSAs was de minimis which is expected to be recognized over a weighted-average period of approximately 0.2 years. The total fair value of RSAs vested was $0.1 million for the nine months ended September 30, 2024.

***Employee Stock Purchase Plan***

As of September 30, 2024, unrecognized stock-based compensation expense related to the Rani Therapeutics Holdings, Inc. 2021 Employee Stock Purchase Plan (the "ESPP") was de minimis which is expected to be recognized over a weighted-average period of approximately 0.2 years. As of September 30, 2024, contributions withheld from employees totaled $0.1 million and are recorded as a component of accrued expenses and other current liabilities in the condensed consolidated balance sheet.

***Stock-Based Compensation Expense***

The following table summarizes the components of stock-based compensation expense resulting from the grant of stock options, RSUs, RSAs, and the ESPP, recorded in the Company's condensed consolidated statement of operations and comprehensive loss (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Research and development | $ 3,563 | $ 5,275 |
| General and administrative | 8,477 | 9,247 |
| Total stock-based compensation | $ 12,040 | $ 14,522 |

**12. Commitments and Contingencies**

***Legal Proceedings***

In the ordinary course of business, the Company may be subject to legal proceedings, claims and litigation as the Company operates in an industry susceptible to patent legal claims. The Company accounts for estimated losses with respect to legal proceedings and claims when such losses are probable and estimable. Legal costs associated with these matters are expensed when incurred.

***Tax Receivable Agreement***

The Company is party to a TRA with certain of the Continuing LLC Owners. As of September 30, 2024, the Company has not recorded a liability under the TRA related to the income tax benefits originating from the exchanges of Paired Interest or non-corresponding Class A Units of Rani LLC as it is not probable that the Company will realize such tax benefits. To the extent the Company is able to realize the income tax benefits associated with the exchanges of Paired Interest or non-corresponding Class A Units of Rani LLC subject to the TRA, the TRA payable would range from zero to $23.1 million at September 30, 2024.

The amounts payable under the TRA will vary depending upon a number of factors, including the amount, character, and timing of the taxable income of the Company in the future. Should the Company determine that the payment of the TRA liability becomes probable at a future date based on new information, any changes will be recorded on the Company's condensed consolidated statement of operations and comprehensive loss at that time.

**13. Long-Term Debt**

In August 2022, the Company entered into a loan and security agreement and related supplement (the "Loan Agreement") with Avenue Venture Opportunities Fund, L.P (the "Lender"). The Loan Agreement provides for term loans (the "Loans") in an aggregate principal amount up to $45.0 million. A Loan of $30.0 million was committed at closing, with $15.0 million funded immediately and $15.0 million available to be drawn between October 1, 2022 and December 31, 2022, which was drawn in December 2022. The remaining $15.0 million of Loans was uncommitted and subject to certain conditions and is no longer available under the Loan Agreement. The purpose of the Loans is for general corporate purposes. In exchange for access to this facility, the Company agreed to issue warrants (Note 9).

Pursuant to the Loan Agreement, the maturity date for the Loans is August 1, 2026 (the "Maturity Date"). The Loan principal is repayable in equal monthly installments beginning September 2024. The Loans bear interest at a variable rate per annum equal to the greater of (A) the prime rate, as published by the Wall Street Journal from time to time plus 5.60% or (B) 10.35%. The Loan Agreement is collateralized by substantially all of the Company's assets, in which the Lender is granted continuing security interests. The Loans includes customary events of default, including instances of a material adverse change in the Company's operations, which may require prepayment of the outstanding Loans. At September 30, 2024, the effective interest rate on the Loans was 15.62% and there were no events of default during the nine months ended September 30, 2024. The Company is also subject to certain covenants. There have been no material adverse events in connection with the Loan Agreement and the substantial doubt regarding our ability to continue as a going concern does not currently constitute a material adverse event under the terms of the Loan Agreement. As of September 30, 2024, the Company was in compliance with all applicable covenants under the Loan Agreement.

As of September 30, 2024, future principal payments for the Company's debt are as follows (in thousands):

| | | |
|---|---|---|
| Year ending December 31, | | |
| 2024 (remaining three months) | $ | 3,750 |
| 2025 | | 15,000 |
| 2026 | | 10,000 |
| Total principal payments | $ | 28,750 |
| Less: amount representing debt discount | | (445) |
| Total long-term debt | $ | 28,305 |
| Less: current portion of long-term debt | | 14,768 |
| Total long-term debt, less current portion | $ | 13,537 |

**14. Income Taxes**

The Company's effective income tax rate was zero for each of the nine months ended September 30, 2024 and 2023. As a result of the exchanges from the date of the Organizational Transactions to September 30, 2024, the Company recorded a $18.9 million deferred tax asset related to income tax benefit associated with the basis of the net assets of Rani LLC. Because of the Company's history of operating losses, the Company believes that recognition of the deferred tax assets arising from such future income tax benefits is currently not more-likely-than-not to be realized and, accordingly, has recognized a full valuation allowance on its deferred tax assets.

There were no material changes to uncertain tax positions for the nine months ended September 30, 2024 and 2023, and the Company does not anticipate material changes within the next twelve months.

**15. Net Loss Per Share**

The following table sets forth the computation of basic and diluted net loss per Class A common share attributable to Rani Holdings (in thousands, except per share data):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2024 | 2023 |
| **Numerator:** | | |
| Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc. | $ (21,071) | $ (26,872) |
| **Denominator:** | | |
| Weighted average Class A common share outstanding—basic and diluted | 27,071 | 25,380 |
| Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.—basic and diluted | $ (0.78) | $ (1.06) |

The following table shows the total outstanding securities considered anti-dilutive and therefore excluded from the computation of diluted net loss per Class A common share attributable to Rani Holdings (in thousands):

| | As of September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Paired Interests | 24,116 | 24,116 |
| Stock options | 10,296 | 6,778 |
| Warrants | 6,570 | 76 |
| Non-corresponding Class A Units | 1,262 | 1,345 |
| Restricted stock units | 893 | 1,413 |
| Shares issuable pursuant to the ESPP | 41 | 82 |
| Restricted stock awards | 11 | 41 |
| | 43,189 | 33,851 |

Shares of Class B Common Stock do not share in the Company's earnings and are not participating securities. Accordingly, separate presentation of loss per share of Class B common stock under the two-class method has not been provided. The outstanding shares of Class B Common Stock were determined to be anti-dilutive for the nine months ended September 30, 2024. Therefore, they are not included in the computation of net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.

**16. Subsequent Events**

***Securities Purchase Agreement***

In October 2024, the Company entered into a securities purchase agreement (the "October Securities Purchase Agreement") with an institutional investor (the "Equity Investor") relating to the issuance and sale of: (i) 3,000,000 shares of its Class A common stock, par value $0.0001 per share, (ii) pre-funded warrants to purchase 333,333 shares of Class A common stock, and (iii) Series C common warrants, which will accompany the Class A common stock and pre-funded warrants, to purchase an aggregate of 3,333,333 shares of Class A common stock (the "October Offering"). The October Offering closed on October 16, 2024. Pursuant to the October Securities Purchase Agreement, Series A common warrants to purchase an aggregate of 3,246,753 shares of Class A common stock issued in the July Offering were cancelled.

The pre-funded warrants are exercisable immediately following the closing date of the October Offering and have an unlimited term and an exercise price of $0.0001 per share. The Series C common warrants are exercisable immediately following the closing date of the October Offering, will expire five years from the date of issuance and will have an exercise price of $3.00 per share. The combined offering price is $3.00 per share of Class A common stock and accompanying Series C common warrant, or in the case of pre-funded warrants, $2.9999 per pre-funded warrant and accompanying Series C common warrant. The aggregate gross proceeds to the Company from the October Offering were approximately $10.0 million, before deducting placement agent fees and other offering expenses payable by the Company, and excluding potential proceeds, if any, from the exercise of the Series C common warrants issued in the October Offering. In October 2024, the pre-funded warrants were fully exercised for de minimis proceeds.

The Series C common warrants include certain rights upon "fundamental transactions" as described in the Series C common warrants. These rights upon "fundamental transactions" include the right of the holders thereof to receive from Rani or a successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of Class A common stock in such fundamental transaction in the amount of the Black Scholes value (as described in the Series C common warrants) of the unexercised portion of the applicable Series C common warrants on the date of the consummation of such fundamental transaction.

Pursuant to the terms of the October Securities Purchase Agreement, until 30 days following the closing of the October Offering, the Company has agreed not to issue, enter into any agreement to issue, or announce the issuance or proposed issuance of any shares of Class A common stock or common stock equivalents, or file or amend any registration statement or prospectus, other than as necessary to maintain the registration of the securities offered thereby. The Company has further agreed not to enter into an agreement involving any new variable rate transactions until January 23, 2025, subject to certain exceptions. In addition, the Company's directors and officers have entered into lock-up agreements with the Company pursuant to which each of them has agreed not to, for a period of 30 days from the closing of the October Offering, offer, sell, transfer or otherwise dispose of the Company's securities, subject to certain exceptions.

***CEO Compensation Reduction***

In November 2023, the Company's Board of Directors ("Board") approved a reduction in the annual salary of Talat Imran, the Company's Chief Executive Officer, from $520,000 to $100,000, effective November 1, 2023 through December 31, 2024 or until such time as the Company receives gross proceeds of $50,000,000 or more, in the aggregate, from equity financing and/or one or more non-dilutive strategic, licensing or partnering transactions (the "Financing Threshold"). In November 2024, the Board approved to extend the reduction in annual salary of Talat Imran through December 31, 2025 or until the Financing Threshold is met.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

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

*You should read the following management's discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes and other information included elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the Securities and Exchange Commission ("SEC"). Some of the information contained in this discussion and analysis or set forth elsewhere in this document, includes forward looking statements that involve risks, uncertainties, and assumptions. Our actual results could differ materially from those discussed in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors" in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2023. Please also see the section titled "Forward Looking Statements."*

*The following discussion contains references to calendar year 2023 and the three and nine months ended September 30, 2024 and 2023, respectively, which represents the condensed consolidated financial results of Rani Therapeutics Holdings, Inc. (the "Company") and its subsidiary, Rani Therapeutics, LLC ("Rani LLC") for the year ended December 31, 2023 and the three and nine months ended September 30, 2024 and 2023, respectively. Unless we state otherwise or the context otherwise requires, the terms "we," "us," "our," and "Rani" and similar references refers to the Company and its consolidated subsidiary.*

**Overview**

We are a clinical stage biotherapeutics company focusing on advancing technologies to enable the administration of biologics and drugs orally, to provide patients, physicians, and healthcare systems with a convenient alternative to painful injections. We are advancing a portfolio of oral therapeutics using our proprietary delivery technology and we are actively pursuing partnering the technology with third party biopharmaceutical companies for the oral delivery of their biologics and drugs.

Our technology comprises a drug-agnostic oral delivery platform, the RaniPill capsule, which is designed to deliver a wide variety of drug substances, including antibodies, proteins, peptides, and oligonucleotides. We are currently developing two configurations of the platform – the RaniPill GO and the RaniPill HC. The RaniPill GO is designed to deliver up to a 3 mg dose of drug in microtablet form with high bioavailability. We have completed three Phase 1 clinical trials using the RaniPill GO. We are also developing a high-capacity version of the RaniPill capsule known as the RaniPill HC, which is intended to enable delivery of drug payloads up to 200µL in liquid form with high bioavailability. We have tested preclinically the RaniPill HC with multiple therapeutics, including antibodies and a peptide. We intend to initiate clinical testing of the RaniPill HC in 2025.

We believe that, together, the RaniPill GO and RaniPill HC could enable us to deliver most biologics currently on the market with convenient, oral dosing.

We do not have any products approved for sale, and we have not yet generated any revenue from sales of a commercial product. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development of the RaniPill capsule, which we expect will take a number of years. Given our stage of development, we have not yet established a commercial organization or distribution capabilities, and we have no experience as a company in marketing drugs or a drug-delivery platform. When, and if, any of our product candidates are approved for commercialization, we plan to develop a commercialization infrastructure or engage commercial sales organizations or distributors for those products in the United States, Europe, Asia, and potentially in certain other key markets. We may also rely on partnerships to provide commercialization infrastructure, including sales, marketing, and commercial distribution.

As is common with biotechnology companies, we rely on third-party suppliers for the supply of raw materials and active pharmaceutical ingredients ("APIs") and drug substances required for the production of our product candidates. In addition, we work with third parties to manufacture and develop biologics and drugs for inclusion in the current RaniPill capsule and RaniPill HC. Design work, prototyping and pilot manufacturing are performed in house, and we have utilized third-party engineering firms to assist with the design of manufacturing lines that support our supply of the current RaniPill capsule and RaniPill HC. Certain of our suppliers of components and materials are single source suppliers. We believe our vertically integrated manufacturing strategy will offer significant advantages, including rapid product iteration, control over our product quality and the ability to rapidly scale our manufacturing capacity. This capability also allows us to develop future generations of products while maintaining the confidentiality of our intellectual property. Our vertically integrated manufacturing strategy will result in material future capital outlays and fixed costs related to constructing and operating a manufacturing facility. We have invested and plan to continue to invest in automated manufacturing production lines for the current RaniPill capsule and RaniPill HC. Those assets deemed to have an alternative future use have been capitalized as property and equipment while those projects related to our assets determined to not have an alternative future use have been expensed as research and development costs.

As of September 30, 2024, our cash, cash equivalents and marketable securities totaled $30.4 million. In July 2024, we entered into a securities purchase agreement (the “July Securities Purchase Agreement”) with an institutional investor relating to the issuance and sale of: (i) 2,800,000 shares of its Class A common stock, (ii) pre-funded warrants to purchase 446,753 shares of Class A common stock, (iii) Series A common warrants, which accompany the Class A common stock and pre-funded warrants, to purchase an aggregate of 3,246,753 shares of Class A common stock (the “Series A Warrants”) and (iv) Series B common warrants, which accompany the Class A common stock and pre-funded warrants, to purchase an aggregate of 3,246,753 shares of Class A common stock (the “July Offering”). The aggregate net proceeds from the July Offering totaled $8.9 million, after deducting placement agent fees and other offering expenses, and excluding potential proceeds, if any, from the exercise of the Series A common warrants and Series B common warrants issued in the July Offering. In August 2024, the pre-funded warrants were fully exercised for de minimis proceeds.

In October 2024, we entered into a securities purchase agreement (the “October Securities Purchase Agreement”) with an institutional investor relating to the issuance and sale of: (i) 3,000,000 shares of our Class A common stock, (ii) pre-funded warrants to purchase 333,333 shares of Class A common stock, and (iii) Series C common warrants, which accompany the Class A common stock and pre-funded warrants, to purchase an aggregate of 3,333,333 shares of Class A common stock (the “October Offering” and collectively with the July Offering, the “Offerings”). Pursuant to the October Securities Purchase Agreement, the Series A Warrants were cancelled. The aggregate gross proceeds from the October Offering were approximately $10.0 million, before deducting placement agent fees and other offering expenses payable by us, and excluding potential proceeds, if any, from the exercise of the pre-funded warrants and Series C common warrants issued in the October Offering. In October 2024, the pre-funded warrants were fully exercised for de minimis proceeds.

We expect to continue to incur losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities. Our existing capital resources, including the net proceeds from the Offerings, our initial public offering in 2021 (“IPO”) and term loans we received under a loan and security agreement and related supplement (the “Loan Agreement”) with Avenue Venture Opportunities Fund, L.P (the “Lender”), will not be sufficient to enable us to initiate any pivotal clinical trials. We will need to raise substantial additional funds in the future in order to complete the development of the RaniPill platform, to complete the clinical development of our product candidates and seek regulatory approval thereof, to expand our manufacturing capabilities, to further develop the RaniPill HC device and to commercialize any of our product candidates. We may seek to raise capital through equity offerings or debt financings, collaboration agreements, or other arrangements with other companies, or through other sources of financing.

***Preclinical Update***

In October 2024, we announced new pharmacokinetic data from a preclinical study evaluating a GLP-1, GIP and glucagon receptors incretin triagonist with a delivery method mimicking the RaniPill route of administration. The pharmacokinetic data provides further evidence of the RaniPill platform’s potential to enable oral delivery of multiple obesity treatments.

**Relationship with InCube Labs, LLC**

See Note 7 to the condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

**Results of Operations**

The results of operations presented below should be reviewed in conjunction with the condensed consolidated financial statements and notes included elsewhere in this Quarterly Report on Form 10-Q. For information with respect to recent accounting pronouncements that are of significance or potential significance to us, see "Note 2. Summary of Significant Accounting Policies" in the "Notes to the Unaudited Condensed Consolidated Financial Statements" contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

***Comparison of the three months ended September 30, 2024 and 2023***

The following table summarizes our results of operations (in thousands):

| | Three Months Ended September 30, | | |
|---|---|---|---|
| | 2024 | 2023 | Change |
| Operating expenses | | | |
| Research and development | $ 6,172 | $ 11,220 | (45.0)% |
| General and administrative | 5,627 | 6,635 | (15.2)% |
| Total operating expenses | $ 11,799 | $ 17,855 | (33.9)% |
| Loss from operations | (11,799) | (17,855) | (33.9)% |
| Other income (expense), net | | | |
| Interest income and other, net | 414 | 839 | (50.7)% |
| Interest expense and other, net | (1,337) | (1,316) | 1.6 % |
| Net loss | $ (12,722) | $ (18,332) | (30.6)% |
| Net loss attributable to non-controlling interest | (5,939) | (9,135) | (35.0)% |
| Net loss attributable to Rani Therapeutics Holdings, Inc. | $ (6,783) | $ (9,197) | (26.2)% |

*Research and Development Expenses*

The following table reflects our research and development costs by nature of expense (in thousands):

| | Three Months Ended September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Payroll, stock-based compensation and related benefits | $ 4,623 | $ 6,464 |
| Facilities, materials and supplies | 1,357 | 1,777 |
| Third-party services | 173 | 2,929 |
| Other | 19 | 50 |
| Total | $ 6,172 | $ 11,220 |

The decrease of $5.0 million in research and development expenses in the three months ended September 30, 2024, as compared to the same period in 2023, was primarily attributed to lower compensation costs of $1.9 million due to reduction in workforce, $2.7 million reduction in third-party services and $0.4 million reduction in materials and supplies due to the timing of certain preclinical and clinical studies.

*General and Administrative Expenses*

The decrease of $1.0 million in general and administrative expenses in the three months ended September 30, 2024, as compared to the same period in 2023, was primarily attributed to lower compensation costs of $0.5 million due to reduction in workforce, $0.4 million reduction in third-party services due to lower directors and officers insurance premiums and $0.3 million reduction in other costs, offset by an increase in facility costs of $0.2 million due to the lease in Fremont, California.

*Other Income (Expense), Net*

The increase of $0.4 million in other expense, net, in the three months ended September 30, 2024, as compared to the same period in 2023, was attributed to a decrease in interest income of $0.4 million from our investment in marketable securities.

***Comparison of the nine months ended September 30, 2024 and 2023***

The following table summarizes our results of operations (in thousands):

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| | 2024 | 2023 | Change |
| Operating expenses | | | |
| Research and development | $ 19,872 | $ 32,018 | (37.9)% |
| General and administrative | 18,484 | 20,647 | (10.5)% |
| Total operating expenses | $ 38,356 | $ 52,665 | (27.2)% |
| Loss from operations | (38,356) | (52,665) | (27.2)% |
| Other income (expense), net | | | |
| Interest income and other, net | 1,403 | 2,626 | (46.6)% |
| Interest expense and other, net | (3,909) | (3,789) | 3.2 % |
| Net loss | $ (40,862) | $ (53,828) | (24.1)% |
| Net loss attributable to non-controlling interest | (19,791) | (26,956) | (26.6)% |
| Net loss attributable to Rani Therapeutics Holdings, Inc. | $ (21,071) | $ (26,872) | (21.6)% |

*Research and Development Expenses*

The following table reflects our research and development costs by nature of expense (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Payroll, stock-based compensation and related benefits | $ 15,048 | $ 21,452 |
| Facilities, materials and supplies | 3,957 | 4,829 |
| Third-party services | 820 | 5,550 |
| Other | 47 | 187 |
| Total | $ 19,872 | $ 32,018 |

The decrease of $12.1 million in research and development expenses in the nine months ended September 30, 2024, as compared to the same period in 2023, was primarily attributed to lower compensation costs of $6.4 million due to reduction in workforce, $4.7 million reduction in third-party services and $0.9 million reduction in materials and supplies due to the timing of certain preclinical and clinical studies.

*General and Administrative Expenses*

The decrease of $2.2 million in general and administrative expenses in the nine months ended September 30, 2024, as compared to the same period in 2023, was primarily attributed to lower compensation costs of $2.0 million due to reduction in workforce, $0.6 million reduction in other costs and $0.3 million reduction in third-party services due to lower directors and officers insurance premiums, offset by an increase in facility costs of $0.7 million due to the lease in Fremont, California.

*Other Income (Expense), Net*

The increase of $1.3 million in other expense, net, in the nine months ended September 30, 2024, as compared to the same period in 2023, was primarily attributed to a decrease in interest income of $1.2 million from our investment in marketable securities and an increase interest expense of $0.1 million from our debt.

**Liquidity and Capital Resources**

***Overview***

We have incurred recurring losses and negative cash flows from operations since inception, including net loss of $40.9 million for nine months ended September 30, 2024. As of September 30, 2024, we had an accumulated deficit of $94.0 million and for nine months ended September 30, 2024, had negative cash flows from operations of $26.8 million. As of September 30, 2024, our cash, cash equivalents and marketable securities totaled $30.4 million. We expect to continue to incur losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities. Our existing capital resources, including the net proceeds from our IPO and term loans we received under the Loan Agreement and the Offerings, will not be sufficient to enable us to initiate any pivotal clinical trials. Based on our available cash resources and current operating plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the nine months ended September 30, 2024 are issued. If we are unable to continue as a going concern, we may have to cease operations and liquidate our assets. We may receive less than the value at which those assets are carried on our condensed consolidated financial statements, and investors may lose all or a part of their investment.

***Financial Update***

In July 2024, we entered into the July Securities Purchase Agreement with an institutional investor relating to the July Offering. The aggregate net proceeds from the July Offering totaled $8.9 million, after deducting placement agent fees and other offering expenses, and excluding potential proceeds, if any, from the exercise of the Series A common warrants and Series B common warrants issued in the July Offering. In August 2024, the pre-funded warrants were fully exercised for de minimis proceeds.

In October 2024, we entered into the October Securities Purchase Agreement with an institutional investor relating to the October Offering. The aggregate gross proceeds from the October Offering were approximately $10.0 million, before deducting placement agent fees and other offering expenses payable by us, and excluding potential proceeds, if any, from the exercise of the Series C common warrants issued in the October Offering. In October 2024, the pre-funded warrants were fully exercised for de minimis proceeds.

In November 2023, our Board of Directors (the “Board”) approved a reduction in the annual salary of Talat Imran, our Chief Executive Officer, from $520,000 to $100,000, effective November 1, 2023 through December 31, 2024 or until such time as we receive gross proceeds of $50,000,000 or more, in the aggregate, from equity financing and/or one or more non-dilutive strategic, licensing or partnering transactions (the “Financing Threshold”). In November 2024, the Board approved to extend the reduction in annual salary of Talat Imran through December 31, 2025 or until the Financing Threshold is met.

In August 2022, we entered into the Loan Agreement with the Lender. The Loan Agreement provides for term loans (the “Loans”) in an aggregate principal amount up to $45.0 million. A Loan of $30.0 million was committed at closing, with $15.0 million funded immediately and $15.0 million available to be drawn between October 1, 2022 and December 31, 2022, which was drawn in December 2022. The remaining $15.0 million of Loans was uncommitted and subject to certain conditions and is no longer available under the Loan Agreement. The Loan Agreement also contains various covenants and restrictive provisions. There have been no material adverse events in connection with the Loan Agreement and the substantial doubt regarding our ability to continue as a going concern does not currently constitute a material adverse event under the terms of the Loan Agreement. The Loan principal is repayable in equal monthly installments beginning September 2024. As of September 30, 2024, we were in compliance with all applicable debt covenants under the Loan Agreement.

In August 2022, we entered into a Controlled Equity Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (collectively the "Agents"), pursuant to which we may offer and sell from time to time through the Agents up to $150.0 million of shares of its Class A common stock, in such share amounts as we may specify by notice to the Agents, in accordance with the terms and conditions set forth in the Sales Agreement. The potential proceeds from the Sales Agreement are expected to be used for general corporate purposes. As of September 30, 2024, we had no sales under the Sales Agreement.

***Tax Receivable Agreement***

See Note 12 to the condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

***Future Funding Requirements***

Notwithstanding the sharing of development costs for the RT-114 program under the ProGen Agreement, our existing capital resources, including the net proceeds from our IPO, the Loans and the Offerings, will not be sufficient to enable us to initiate any pivotal clinical trials with respect to any of our product candidates. We will need to raise substantial additional funds in the future in order to complete the development of the RaniPill platform, to complete the clinical development of our product candidates and seek regulatory approval thereof, to expand our manufacturing capabilities, to further develop the RaniPill HC device and to commercialize any of our product candidates.

To date, we have not generated any commercial product revenue. We do not expect to generate any commercial product revenue unless and until we obtain regulatory approval and commercialize any of our commercial product candidates, and we do not know when, or if at all, that will occur. We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. Our primary uses of cash are to fund our operations, which consist primarily of research and development expenses related to our programs, manufacturing automation and scaleup, and general and administrative expenses. We expect our expenses to continue to increase in connection with our ongoing activities as we continue to advance the RaniPill GO, RaniPill HC and our product candidates.

We may seek to raise capital through equity offerings or debt financings, which may include ATM Sales, collaboration agreements, or other arrangements with other companies, or through other sources of financing. Adequate additional 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 consolidated financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the progress, costs, trial design, results of and timing of our preclinical studies and clinical trials;
- the progress, costs, and results of our research pipeline;
- the willingness of the FDA, or other regulatory authorities to accept data from our clinical trials, as well as data from our completed and planned clinical trials and preclinical studies and other work, as the basis for review and approval of our product candidates or collaborator drugs or biologics paired with the RaniPill GO and/or RaniPill HC for various indications;
- the outcome, costs, and timing of seeking and obtaining FDA and any other regulatory approvals;
- the number and characteristics of product candidates that we pursue;
- our ability to manufacture sufficient quantities of the RaniPill capsules;
- our need to expand our research and development activities;
- the costs associated with manufacturing our product candidates, including establishing commercial supplies and sales, marketing, and distribution capabilities;
- the costs associated with securing and establishing commercial infrastructure;
- the costs of acquiring, licensing, or investing in businesses, product candidates, and technologies;
- our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or other intellectual property rights;
- our need and ability to retain key management and hire scientific, technical, business, and engineering personnel;
- the effect of competing drugs and product candidates and other market developments;
- the timing, receipt, and amount of sales from our potential products, if approved;
- our ability to establish strategic collaborations;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- security breaches, data losses or other disruptions affecting our information systems;
- our ability to realize savings from any restructuring plans or cost-containment measures we may implement; and

- the economic and other terms, timing of and success of any collaboration, licensing, or other arrangements which we may enter in the future.

Pursuant to the terms of the October Securities Purchase Agreement, until 30 days following the closing of the October Offering, we agreed not to issue, enter into any agreement to issue, or announce the issuance or proposed issuance of any shares of Class A common stock or common stock equivalents, or file or amend any registration statement or prospectus, other than as necessary to maintain the registration of the securities offered in the October Offering. We further agreed not to enter into an agreement involving any new variable rate transactions until January 23, 2025, subject to certain exceptions. These restrictions could prevent us from raising additional capital that we might otherwise be able to raise.

If we raise additional capital through debt financing, we may be subject to covenants that restrict our operations including limitations on our ability to incur liens or additional debt, pay dividends, make certain investments, and 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. If we raise funds through collaborations, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, product candidates or grant licenses on terms that may not be favorable to us. 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 delay investments in our manufacturing scale-up and automation. In addition, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets. Furthermore, this Quarterly Report on Form 10-Q contains statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all.

The following table summarizes our cash, cash equivalents and marketable securities:

| | September 30, 2024 | December 31, 2023 |
|---|---|---|
| Cash and cash equivalents | $ 4,277 | $ 5,864 |
| Marketable securities | 26,127 | 42,675 |
| Total cash, cash equivalents and marketable securities | $ 30,404 | $ 48,539 |

As of September 30, 2024, we had cash and cash equivalents and marketable securities of $30.4 million, compared to $48.5 million as of December 31, 2023. Based on our available cash resources and current operating plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the nine months ended September 30, 2024 are issued. Our existing capital resources, including the net proceeds from our IPO, Loans and the Offerings, will not be sufficient to fund our projected operating requirements for a twelve-month period from the issuance of our financial statements.

***Cash Flows***

The following table summarizes our cash flows for the periods presented (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2024 | 2023 |
| Net cash used in operating activities | $ (26,841) | $ (38,758) |
| Net cash provided by investing activities | 17,288 | 16,586 |
| Net cash provided by financing activities | 7,966 | 137 |
| Net decrease in cash, cash equivalents and restricted cash equivalents | $ (1,587) | $ (22,035) |

***Operating Activities***

Net cash used in operating activities for the nine months ended September 30, 2024 was $26.8 million, which was primarily attributable to a net loss of $40.9 million and net accretion and amortization of investments in marketable securities of $0.9 million, partially offset by stock-based compensation expense of $12.0 million and depreciation and amortization expense of $0.8 million. Additionally, there was an increase in accounts payable of $0.9 million, an increase in deferred revenue of $0.6 million and an increase of $0.3 million in prepaid expenses and other current assets for the nine months ended September 30, 2024.

Net cash used in operating activities for the nine months ended September 30, 2023 was $38.8 million, which was primarily attributable to a net loss of $53.8 million and net accretion and amortization of investments in marketable securities of $1.9 million, partially offset by stock-based compensation expense of $14.5 million and depreciation and amortization expense of $0.6 million. Additionally, there was an increase in accrued expenses and other current liabilities of $1.6 million for the nine months ended September 30, 2023.

***Investing Activities***

For the nine months ended September 30, 2024, net cash provided by investing activities was $17.3 million, which primarily consisted of $57.3 million in proceeds from maturities of marketable securities partially offset by $39.7 million in purchases of marketable securities and $0.2 million in purchases of property and equipment.

For the nine months ended September 30, 2023, net cash provided by investing activities was $16.6 million consisting of $81.5 million in proceeds from maturities of marketable securities partially offset by $63.9 million and $1.0 million in purchases of marketable securities and property and equipment, respectively.

***Financing Activities***

For the nine months ended September 30, 2024, net cash provided by financing activities was $8.0 million, which primarily consisted of net proceeds of $8.9 million from the July Offering and $0.2 million from the issuance of common stock under employee stock purchase plan, partially offset by $1.3 million repayment of debt.

For the nine months ended September 30, 2023, net cash provided by financing activities was de minimis.

***Contractual Obligations and Other Commitments***

As of September 30, 2024, there have been no material changes to our contractual obligations and other commitments compared to those disclosed in our Annual Report on Form 10-K

**Critical Accounting Estimates**

We prepare our condensed consolidated financial statements in accordance with U.S. generally accepted accounting principles, which require our management to make estimates that affect the reported amounts of assets, liabilities and disclosures of contingent assets and liabilities at the balance sheet dates, as well as the reported amounts of revenues and expenses during the reporting periods. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations would be affected. We base our estimates on our own historical experience and other assumptions that we believe are reasonable after taking account of our circumstances and expectations for the future based on available information. We evaluate these estimates on an ongoing basis.

We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. There are items within our condensed consolidated financial statements that require estimation but are not deemed critical, as defined above.

**Recently Adopted Accounting Standards**

See Note 2 to the condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

**Other Information**

*JOBS Act Accounting Election*

We are an "emerging growth company" within the meaning of the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). The JOBS Act permits an emerging growth company like us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are electing to use this extended transition period and we will therefore comply with new or revised accounting standards on the earlier of (i) when they apply to private companies; or (ii) when we lose our emerging growth company status. As a result, our financial statements may not be comparable with companies that comply with public company effective dates for accounting standards. We also rely on other exemptions provided by the JOBS Act, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act unless we cease to be an emerging growth company.

We will remain an emerging growth company until the earliest of (1) December 31, 2026 (the last day of the fiscal year following the fifth anniversary of the closing of our IPO), (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which would occur if the market value of our Class A common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

**Item 4. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(e) and 15(d)-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2024.

**Changes in Internal Control over Financial Reporting**

There have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during the three months ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Inherent Limitations on Effectiveness of Controls**

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost–effective control system, misstatements due to error or fraud may occur and not be detected.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

### Item 1A. Risk Factors

Other than as described below, management believes that there have been no significant changes to the risk factors associated with our business as compared to those disclosed in Part 1, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2023.

***Our collaboration agreement with ProGen Co., Ltd. includes certain restrictions and obligations that may limit our flexibility in developing and commercializing RT-114 or require us to bear costs we otherwise would not incur.***

In June 2024, we entered into a Collaboration Agreement with ProGen for the worldwide development and commercialization of RT-114, a GLP-1/GLP-2 dual agonist in the RaniPill® HC capsule. Under the terms of the ProGen Agreement, the parties will share equally the costs and revenues from development and commercialization of RT-114. Each party has certain rights, restrictions and obligations under the ProGen Agreement with respect to the development, manufacture and commercialization of RT-114, including certain rights to provide input on or approve activities of the other party or costs related thereto. As a result, we may not be able to develop and commercialize RT-114 in the manner or timeframe we believe to be most advantageous, and may be obligated to share costs that we otherwise would not incur. In addition, under the terms of the ProGen Agreement, each party has the right to opt-out of the collaboration, including the cost and revenue sharing, for RT-114, in which case the continuing party would bear all costs for further development, manufacture and commercialization of RT-114, other than certain costs already then-approved, and receive all future revenues from the program, subject to a low-to-mid single-digit royalty to the other party, depending on when the opt-out occurred. If ProGen were to opt-out, we would bear all such costs for further development, manufacture and commercialization of RT-114.

***Negative results arising from ProGen's development or future commercialization of PG-102, the therapeutic compound used in RT-114, could have materially adverse effects on our development of RT-114, or limit the commercial profile of an approved label for or result in limiting the commercial opportunity for RT-114, if approved.***

The therapeutic compound utilized in RT-114 is a GLP-1/GLP-2 dual agonist from ProGen known as PG-102. ProGen is developing PG-102, independent of our collaboration, as a subcutaneous injection for obesity and type-II diabetes. ProGen may develop PG-102 for other indications. ProGen's PG-102 is in Phase 1 clinical testing. If ProGen's clinical or preclinical testing of PG-102 results in data that is negative, or perceived to be negative, including without limitation safety concerns, adverse events or uncompetitive or poor efficacy data, or if ProGen encounters challenges obtaining regulatory approval for or commercial success with PG-102, such results could materially adversely affect the development, potential for regulatory approval for and/or commercial opportunity of RT-114, since RT-114 utilizes the same compound. In addition, if ProGen, itself or through a partner, succeeds in developing, obtaining regulatory approval for, and commercializing PG-102 outside of our collaboration, that product could compete with RT-114 and have a material adverse effect on the commercial opportunity for RT-114.

### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

### Item 3. Defaults Upon Senior Securities

None.

### Item 4. Mine Safety Disclosures

Not applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

The following is a list of all exhibits filed or furnished as part of this report:

| Exhibit Number | Description |
|---|---|
| 3.1 | Amended and Restated Certificate of Incorporation of the Registrant as currently in effect (incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 26, 2021). |
| 3.2 | Amended and Restated Bylaws of the Registrant as currently in effect (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 9, 2021). |
| 10.1* | Amendment to Securities Purchase Agreement and Series B Common Stock Purchase Warrant dated September 23, 2024 between Rani Therapeutics Holdings, Inc. and the investors specified therein. |
| 31.1* | 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. |
| 31.2* | 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. |
| 32.1*† | Certification of Principal Executive Officer and 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 – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document. |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

* Filed herewith.

† The certifications attached as Exhibit 32.1 which accompanies this Quarterly Report on Form 10-Q, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.

**SIGNATURES**

Pursuant to the requirements 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.

Rani Therapeutics Holdings, Inc.

Date: November 14, 2024 By: /s/ Talat Imran

**Talat Imran**
*Chief Executive Officer*
*(Principal Executive Officer)*

Date: November 14, 2024 By: /s/ Svai Sanford

**Svai Sanford**
*Chief Financial Officer*
*(Principal Financial and Accounting Officer)*

**Exhibit 10.1**

**AMENDMENT TO SECURITIES PURCHASE AGREEMENT AND**

**SERIES B COMMON STOCK PURCHASE WARRANT**

This Amendment to Securities Purchase Agreement and Series B Common Stock Purchase Warrant (the "Amendment") is entered into by and between (the "Holder") and Rani Therapeutics Holdings, Inc. (the "Company"), effective as of July 23, 2024 ("Amendment Effective Date").

Whereas, Company issued to Holder on July 23, 2024 a Series B Common Stock Purchase Warrant (the "Series B Warrant") in accordance with that certain Securities Purchase Agreement, dated July 22, 2024, among the Company and Holder (the "Purchase Agreement"); and

Whereas, Company and Holder desire to amend the Purchase Agreement and Series B Warrant as set forth herein.

Now, Therefore, in consideration of the premises and mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Company and Holder, intending to be legally bound, do hereby agree as follows:

1. Definitions. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in the Purchase Agreement.

2. Fundamental Transaction. The definition of "Black Scholes Value" as set forth in Section 3(d) (Fundamental Transaction) of the Series B Warrant is hereby amended and replaced, effective as of the Amendment Effective Date, as follows:

> ""Black Scholes Value" means the value of this Warrant based on the Black-Scholes Option Pricing Model obtained from the "OV" function on Bloomberg determined as of the day of consummation of the applicable contemplated Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date, (B) the 100 day volatility obtained from the HVT function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the public announcement of the applicable contemplated Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the sum of the price per share being offered in cash, if any, plus the value of any non-cash consideration, if any, being offered in such Fundamental Transaction and, (D) a remaining option time equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date and (E) a zero cost of borrow."

3. Subsequent Equity Sales. Section 4.11(a) of the Purchase Agreement is hereby amended and replaced, effective as of the Amendment Effective Date, as follows:

> "From the date hereof until ninety (90) days after the Closing Date, neither the Company nor any Subsidiary shall (i) issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of Common Stock or Common Stock Equivalents or (ii) file any registration statement or amendment or supplement thereto, other than the Prospectus Supplement or the filing of a registration statement on Form S-8 in connection with any employee benefit plan."

4. No Further Amendment. Except as amended by this Amendment, the Purchase Agreement and the Series B Warrant remain unaltered and shall remain in full force and effect.

5. Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Amendment shall be determined in accordance with the provisions of the Purchase Agreement.

*(Signature Page Immediately Follows)*

IN WITNESS WHEREOF, each of Company and Holder have caused this Amendment to be executed by a duly authorized representative.

**RANI THERAPEUTICS HOLDINGS, INC.**

By: /s/ Svai Sanford
Name: Svai Sanford
Title: CFO
Date: 09/23/2024

By:
Name:
Title:
Date: September 22, 2024

**Exhibit 31.1**

**CERTIFICATION**

I, Talat Imran, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Rani Therapeutics Holdings, 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 14, 2024

/s/ Talat Imran

Talat Imran
Chief Executive Officer
*(Principal Executive Officer)*

**Exhibit 31.2**

**CERTIFICATION**

I, Svai Sanford, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Rani Therapeutics Holdings, 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 14, 2024

/s/ Svai Sanford
Svai Sanford
Chief Financial Officer
*(Principal Financial and Accounting Officer)*

**Exhibit 32.1**

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Talat Imran, Chief Executive Officer of Rani Therapeutics Holdings, Inc. (the "Company"), and Svai Sanford, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

**1.** The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Dated: November 14, 2024

**In Witness Whereof**, the undersigned have set their hands hereto as of the 14th day of November, 2024

| | |
|---|---|
| /s/ Talat Imran | /s/ Svai Sanford |
| Talat Imran | Svai Sanford |
| Chief Executive Officer | Chief Financial Officer |
| *(Principal Executive Officer)* | *(Principal Financial and Accounting Officer)* |

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Rani Therapeutics Holdings, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.