

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 March 31, 2025

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  
(State or other jurisdiction of  
incorporation or organization)  
2051 Ringwood Avenue  
San Jose, California  
(Address of principal executive offices)

86-3114789  
(I.R.S. Employer  
Identification No.)

95131  
(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<br>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 May 12, 2025, the registrant had 33,570,253 shares of Class A common stock, \$0.0001 par value per share, outstanding, 23,971,852 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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#### **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:

- our ability to raise additional capital to fund our existing operations and continue as a going concern;
- our plans to improve our liquidity and financial position in response to the substantial doubt about our ability to continue as a going concern;
- 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 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, including 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 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 31, 2025. 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)

|   | March 31,<br>2025<br>(Unaudited) | December 31,<br>2024 |
|---|----------------------------------|----------------------|
| <b>Assets</b>   |                                  |                      |
| Current assets:   |                                  |                      |
| Cash and cash equivalents   | \$ 10,111                        | \$ 3,762             |
| Accounts receivable   | 600                              | —                    |
| Contract asset  | —                                | 428                  |
| Marketable securities   | 5,742                            | 23,877               |
| Prepaid expenses and other current assets   | 1,330                            | 1,677                |
| Total current assets  | 17,783                           | 29,744               |
| Property and equipment, net   | 1,348                            | 1,548                |
| Operating lease right-of-use asset  | 4,748                            | 5,096                |
| Other assets  | 246                              | 246                  |
| Total assets  | \$ 24,125                        | \$ 36,634            |
| <b>Liabilities and Stockholders' Equity</b>   |                                  |                      |
| Current liabilities:  |                                  |                      |
| Accounts payable  | \$ 1,520                         | \$ 1,359             |
| Accrued expenses and other current liabilities  | 2,285                            | 2,073                |
| Current portion of long-term debt   | 15,000                           | 15,000               |
| Current portion of operating lease liability  | 1,325                            | 1,459                |
| Total current liabilities   | 20,130                           | 19,891               |
| Long-term debt, less current portion  | 5,921                            | 9,613                |
| Operating lease liability, less current portion   | 3,423                            | 3,637                |
| Total liabilities   | 29,474                           | 33,141               |
| Commitments and contingencies (Note 12)   |                                  |                      |
| Stockholders' equity:   |                                  |                      |
| Preferred stock, \$0.0001 par value - 20,000 shares authorized; none issued and outstanding as of March 31, 2025 and December 31, 2024                                  | —                                | —                    |
| Class A common stock, \$0.0001 par value - 800,000 shares authorized; 33,570 and 33,430 issued and outstanding as of March 31, 2025 and December 31, 2024, respectively | 3                                | 3                    |
| Class B common stock, \$0.0001 par value - 40,000 shares authorized; 23,972 issued and outstanding as of March 31, 2025 and December 31, 2024                           | 2                                | 2                    |
| Class C common stock, \$0.0001 par value - 20,000 shares authorized; none issued and outstanding as of March 31, 2025 and December 31, 2024                             | —                                | —                    |
| Additional paid-in capital  | 107,108                          | 104,889              |
| Accumulated other comprehensive gain  | 2                                | 5                    |
| Accumulated deficit   | (110,171)                        | (102,907)            |
| Total stockholders' (deficit)/equity attributable to Rani Therapeutics Holdings, Inc.   | (3,056)                          | 1,992                |
| Non-controlling interest  | (2,293)                          | 1,501                |
| Total stockholders' (deficit)/equity  | (5,349)                          | 3,493                |
| Total liabilities and stockholders' equity  | \$ 24,125                        | \$ 36,634            |

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)

|  | <u>Three Months Ended March 31,</u> |                    |
|--|-------------------------------------|--------------------|
|  | <u>2025</u>                         | <u>2024</u>        |
| Contract revenue   | \$ 172                              | \$ —               |
| Operating expenses   |                                     |                    |
| Research and development   | 6,570                               | 7,586              |
| General and administrative   | 5,615                               | 6,448              |
| Total operating expenses   | <u>\$ 12,185</u>                    | <u>\$ 14,034</u>   |
| Loss from operations   | (12,013)                            | (14,034)           |
| Other income (expense), net  |                                     |                    |
| Interest income and other, net   | 218                                 | 549                |
| Interest expense and other, net  | (943)                               | (1,294)            |
| Net loss   | <u>\$ (12,738)</u>                  | <u>\$ (14,779)</u> |
| Net loss attributable to non-controlling interest  | (5,474)                             | (7,296)            |
| Net loss attributable to Rani Therapeutics Holdings, Inc.  | <u>\$ (7,264)</u>                   | <u>\$ (7,483)</u>  |
| Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.,<br>basic and diluted | <u>\$ (0.22)</u>                    | <u>\$ (0.29)</u>   |
| Weighted-average Class A common shares outstanding—basic and diluted                                     | <u>33,440</u>                       | <u>26,034</u>      |

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)

|   | <u>Three Months Ended March 31,</u> |             |
|---|-------------------------------------|-------------|
|   | <u>2025</u>                         | <u>2024</u> |
| Net loss  | \$ (12,738)                         | \$ (14,779) |
| Other comprehensive loss  |                                     |             |
| Net unrealized (loss) gain on marketable securities                 | (6)                                 | 1           |
| Comprehensive loss  | \$ (12,744)                         | \$ (14,778) |
| Comprehensive loss attributable to non-controlling interest         | (5,477)                             | (7,295)     |
| Comprehensive loss attributable to Rani Therapeutics Holdings, Inc. | \$ (7,267)                          | \$ (7,483)  |

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' (DEFICIT)/EQUITY**  
(in thousands)  
(Unaudited)

|   | Class A Common Stock |        | Class B Common Stock |        | Additional<br>Paid In<br>Capital | Accumulated<br>Other<br>Comprehensive<br>Gain | Accumulated<br>Deficit | Non-<br>Controlling<br>Interest | Total<br>Stockholders'<br>(Deficit)/Equi<br>ty |
|---|----------------------|--------|----------------------|--------|----------------------------------|---|------------------------|---------------------------------|--|
|   | Shares               | Amount | Shares               | Amount |                                  |   |                        |                                 |  |
| Balance at December 31, 2024  | 33,430               | \$ 3   | 23,972               | \$ 2   | \$ 104,889                       | \$ 5  | \$ (102,907)           | \$ 1,501                        | \$ 3,493                                       |
| Issuance of common stock under employee equity plans, net of shares withheld for tax settlement | 140                  | —      | —                    | —      | (23)                             | —   | —                      | —                               | (23)   |
| Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC          | —                    | —      | —                    | —      | 1                                | —   | —                      | (1)                             | —  |
| Stock-based compensation  | —                    | —      | —                    | —      | 2,241                            | —   | —                      | 1,684                           | 3,925  |
| Net loss  | —                    | —      | —                    | —      | —                                | —   | (7,264)                | (5,474)                         | (12,738)                                       |
| Other comprehensive loss  | —                    | —      | —                    | —      | —                                | (3)   | —                      | (3)                             | (6)  |
| Balance at March 31, 2025   | 33,570               | \$ 3   | 23,972               | \$ 2   | \$ 107,108                       | \$ 2  | \$ (110,171)           | \$ (2,293)                      | \$ (5,349)                                     |

|  | Class A Common Stock |        | Class B Common Stock |        | Additional<br>Paid In<br>Capital | Accumulated<br>Other<br>Comprehensive<br>Loss | Accumulated<br>Deficit | Non-<br>Controlling<br>Interest | Total<br>Stockholders'<br>Equity |
|--|----------------------|--------|----------------------|--------|----------------------------------|---|------------------------|---------------------------------|----------------------------------|
|  | Shares               | Amount | Shares               | Amount |                                  |   |                        |                                 |                                  |
| 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                        |

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)

|  | <b>Three Months Ended March 31,</b> |                 |
|--|-------------------------------------|-----------------|
|  | <b>2025</b>                         | <b>2024</b>     |
| <b>Cash flows from operating activities</b>  |                                     |                 |
| Net loss   | \$ (12,738)                         | \$ (14,779)     |
| Adjustments to reconcile net loss to net cash used in operating activities:                                      |                                     |                 |
| Stock-based compensation expense   | 3,925                               | 3,870           |
| Depreciation and amortization  | 251                                 | 248             |
| Non-cash operating lease expense   | 477                                 | 378             |
| Amortization of debt discount and issuance costs   | 58                                  | 58              |
| Net accretion and amortization of investments in marketable securities   | (150)                               | (340)           |
| Changes in operating assets and liabilities:   |                                     |                 |
| Accounts receivable  | (600)                               | —               |
| Contract asset   | 428                                 | —               |
| Prepaid expenses and other current assets  | 347                                 | 499             |
| Accounts payable   | 161                                 | 158             |
| Accrued expenses and other current liabilities   | 170                                 | 884             |
| Operating lease liabilities  | (478)                               | (378)           |
| Net cash used in operating activities  | (8,149)                             | (9,402)         |
| <b>Cash flows from investing activities</b>  |                                     |                 |
| Proceeds from maturities of marketable securities  | 21,000                              | 20,350          |
| Purchases of marketable securities   | (2,720)                             | (10,038)        |
| Purchases of property and equipment  | (51)                                | (18)            |
| Net cash provided by investing activities  | 18,229                              | 10,294          |
| <b>Cash flows from financing activities</b>  |                                     |                 |
| Proceeds from employee stock purchase plan   | 42                                  | 121             |
| Tax withholdings paid on behalf of employees for net share settlement  | (23)                                | —               |
| Repayment of debt  | (3,750)                             | —               |
| Net cash (used in)/provided by financing activities  | (3,731)                             | 121             |
| Net increase in cash, cash equivalents and restricted cash equivalents   | 6,349                               | 1,013           |
| Cash, cash equivalents and restricted cash equivalents, beginning of period                                      | 4,262                               | 6,364           |
| Cash, cash equivalents and restricted cash equivalents, end of period  | <u>\$ 10,611</u>                    | <u>\$ 7,377</u> |
| <b>Supplemental disclosures of non-cash investing and financing activities</b>                                   |                                     |                 |
| Interest income receivable included in prepaid expenses and other current assets                                 | <u>\$ 17</u>                        | <u>\$ 166</u>   |
| Right-of-use assets obtained in exchange for new operating lease liabilities                                     | <u>\$ —</u>                         | <u>\$ 4,731</u> |
| Exchanges of non-corresponding Class A Units of Rani LLC   | <u>\$ —</u>                         | <u>\$ 298</u>   |
| Remeasurement of operating lease right-of-use assets   | <u>\$ —</u>                         | <u>\$ 589</u>   |
| Property and equipment purchases included in accounts payable and accrued expenses and other current liabilities | <u>\$ —</u>                         | <u>\$ 48</u>    |

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

**RANI THERAPEUTICS HOLDINGS, INC.**  
**NOTES TO THE 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 biopharmaceuticals 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.

***Organizational Transactions***

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 March 31, 2025, 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 1,229,630 shares of the Company's Class A common stock.

***Liquidity and Going Concern***

The Company has incurred recurring losses since its inception, including net losses of \$12.7 million for the three months ended March 31, 2025. As of March 31, 2025, the Company had an accumulated deficit of \$110.2 million and for the three months ended March 31, 2025, had negative cash flows from operations of \$8.1 million. As of March 31, 2025, cash, cash equivalents and marketable securities totaled \$15.9 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 three months ended March 31, 2025 are issued. The Company's existing capital resources 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.

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" pursuant to its Controlled Equity Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC, 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.

## 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").

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 months ended March 31, 2025 are not necessarily indicative of the results that may be expected for the year ending December 31, 2025 or for any future period.

The consolidated balance sheet as of December 31, 2024 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 2024 consolidated financial statements and notes included in the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2025.

### *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, 2024. Except as noted below, there have been no material changes in the Company's significant accounting policies during the three months ended March 31, 2025.

### *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 three months ended March 31, 2025 and 2024:

|  | Three Months Ended March 31, |                 |
|--|------------------------------|-----------------|
|  | 2025                         | 2024            |
| Cash and cash equivalents                                    | \$ 10,111                    | \$ 6,877        |
| Restricted cash equivalents                                  | 500                          | 500             |
| Total cash, cash equivalents and restricted cash equivalents | <u>\$ 10,611</u>             | <u>\$ 7,377</u> |

### Accounts Receivable and Allowance for Credit Losses

Accounts receivable primarily consist of amounts due from customers for services performed. The Company's expected credit losses are developed using an estimated loss rate method that considers historical collection experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. The estimated loss rates are applied to trade receivables with similar risk characteristics such as the length of time the balance has been outstanding, liquidity and financial position of the customer, and the geographic location of the customer. In certain instances, the Company may identify individual accounts receivable assets that do not share risk characteristics with other accounts receivable, in which case the Company records its expected credit losses on an individual asset basis. As of March 31, 2025, there was no allowance for credit losses, nor write-offs or recoveries recognized.

### Recently Issued Accounting Pronouncements

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 consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03 "Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40)" to provide disaggregated information about certain income statement costs and expenses. ASU 2024-03 is effective for the Company's annual periods beginning January 1, 2027, with early adoption permitted. The Company is evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

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

The following tables summarize 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 March 31, 2025 |                  |                   |                      |
|---|----------------------|------------------|-------------------|----------------------|
|   | Amortized Cost       | Unrealized Gains | Unrealized Losses | Estimated Fair Value |
| Current assets:   |                      |                  |                   |                      |
| Cash equivalents:   |                      |                  |                   |                      |
| Money market funds  | \$ 3,188             | \$ —             | \$ —              | \$ 3,188             |
| Total cash equivalents  | 3,188                | —                | —                 | 3,188                |
| Restricted cash equivalents:  |                      |                  |                   |                      |
| Money market funds  | 500                  | —                | —                 | 500                  |
| Total cash equivalents and restricted cash equivalents                        | 3,688                | —                | —                 | 3,688                |
| Marketable securities:  |                      |                  |                   |                      |
| U.S. Treasuries and agencies  | 10,727               | —                | (1)               | 10,726               |
| Total cash equivalents, restricted cash equivalents and marketable securities | \$ 14,415            | \$ —             | \$ (1)            | \$ 14,414            |

  

|   | As of December 31, 2024 |                  |                   |                      |
|---|-------------------------|------------------|-------------------|----------------------|
|   | Amortized Cost          | Unrealized Gains | Unrealized Losses | Estimated Fair Value |
| Current assets:   |                         |                  |                   |                      |
| Cash equivalents:   |                         |                  |                   |                      |
| Money market funds  | \$ 404                  | \$ —             | \$ —              | \$ 404               |
| Total cash and cash equivalents   | 404                     | —                | —                 | 404                  |
| Restricted cash equivalents:  |                         |                  |                   |                      |
| Money market funds  | 500                     | —                | —                 | 500                  |
| Total cash equivalents and restricted cash equivalents                        | 904                     | —                | —                 | 904                  |
| Marketable securities:  |                         |                  |                   |                      |
| U.S. Treasuries and agencies  | 24,871                  | 5                | —                 | 24,876               |
| Total cash equivalents, restricted cash equivalents and marketable securities | \$ 25,775               | \$ 5             | \$ —              | \$ 25,780            |

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 March 31, 2025, 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 March 31, 2025. As of March 31, 2025 and December 31, 2024, interest income receivable recorded as a component of prepaid expenses and other current assets on the condensed consolidated balance sheet was de minimis.

#### 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 indicates the level of inputs used in such measurements (in thousands):

|                              | As of March 31, 2025 |             |             |                  |
|------------------------------|----------------------|-------------|-------------|------------------|
|                              | Level 1              | Level 2     | Level 3     | Total            |
| Assets:                      |                      |             |             |                  |
| Cash equivalents:            |                      |             |             |                  |
| Money market funds           | \$ 3,188             | \$ —        | \$ —        | \$ 3,188         |
| Restricted cash equivalents: |                      |             |             |                  |
| Money market funds           | 500                  | —           | —           | 500              |
| Marketable securities        |                      |             |             |                  |
| U.S. Treasuries and agencies | 10,726               | —           | —           | 10,726           |
| Total assets                 | <u>\$ 14,414</u>     | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 14,414</u> |

  

|                              | As of December 31, 2024 |             |             |                  |
|------------------------------|-------------------------|-------------|-------------|------------------|
|                              | Level 1                 | Level 2     | Level 3     | Total            |
| Assets:                      |                         |             |             |                  |
| Cash equivalents:            |                         |             |             |                  |
| Money market funds           | \$ 404                  | \$ —        | \$ —        | \$ 404           |
| Restricted cash equivalents: |                         |             |             |                  |
| Money market funds           | 500                     | —           | —           | 500              |
| Marketable securities        |                         |             |             |                  |
| U.S. Treasuries and agencies | 24,876                  | —           | —           | 24,876           |
| Total assets                 | <u>\$ 25,780</u>        | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 25,780</u> |

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):

|  | March 31,<br>2025 | December 31,<br>2024 |
|--|-------------------|----------------------|
| Accrued interest                                     | \$ 1,039          | \$ 931               |
| Accrued rent   | 333               | 329                  |
| Accrued professional fees                            | 267               | 107                  |
| Payroll and related costs                            | 247               | 353                  |
| Accrued preclinical and clinical trial costs         | 89                | 70                   |
| Other  | 310               | 283                  |
| Total accrued expenses and other current liabilities | <u>\$ 2,285</u>   | <u>\$ 2,073</u>      |

## 6. Evaluation and Collaborative Arrangements

### *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, which was concluded to be a single performance obligation with an enforceable right to payment. 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. For the period ended March 31, 2025, \$0.2 million in contract revenue was recognized for evaluation services performed.

### *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 parties share responsibility for the development of RT-114 worldwide, with the Company leading such development for preclinical activities through Phase 1 clinical trials. After initiation of the first Phase 2 clinical trial, the Company will lead development and commercialization of the Product in the United States, Canada, Europe (including the United Kingdom) and Australia, and ProGen will lead development and commercialization 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 March 31, 2025, reimbursement due from ProGen recorded as contra-research and development expense was de minimis.

## 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 had 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 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. The Occupancy Services for the facility in Milpitas, California expired in August 2024. The Occupancy Services for the facility in San Antonio, Texas terminated in June 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 March 31, |      |      |     |
|----------------------------|------------------------------|------|------|-----|
|                            | 2025                         |      | 2024 |     |
| Research and development   | \$                           | 186  | \$   | 306 |
| General and administrative |                              | (14) |      | 49  |
| Total                      | \$                           | 172  | \$   | 355 |

As of March 31, 2025, 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 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.

### ***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 three months ended March 31, 2025 and 2024, these parties to the TRA exchanged zero Paired Interests, respectively, that resulted in tax benefits subject to the TRA.

### ***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 three months ended March 31, 2025 and 2024, certain related parties that are party to the Rani LLC Agreement exchanged zero Paired Interests, respectively, 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. The Company accounted for its Occupancy Services in San Antonio, Texas as a short-term lease. 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 Company accounted for the March 2024 extension for its Occupancy Services in Milpitas, California as a short-term lease. 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 March 31, 2025 and 2024 and for the three months ended March 31, 2025 and 2024, respectively, related to the Company's leases was as follows (in thousands):

|  | March 31,                    |        |
|--|------------------------------|--------|
|  | 2025                         | 2024   |
| Weighted-average remaining lease term (in years)     | 3.7                          | 4.4    |
| Weighted-average discount rate                       | 10.4%                        | 10.4%  |
|  | Three Months Ended March 31, |        |
|  | 2025                         | 2024   |
| <b>Cash flows</b>                                    |                              |        |
| Cash paid for amounts included in lease liabilities: |                              |        |
| Operating cash flows used for operating leases       | \$ 473                       | \$ 180 |

As of March 31, 2025, minimum annual rental payments under the Company's operating lease agreements are as follows (in thousands), excluding short-term leases:

|  |          |
|--|----------|
| Year ending December 31,                           |          |
| 2025 (remaining nine months)                       | \$ 1,428 |
| 2026   | 1,229    |
| 2027   | 1,278    |
| 2028   | 1,330    |
| 2029   | 458      |
| Total undiscounted future minimum lease payments   | \$ 5,723 |
| Less: Imputed interest                             | (975)    |
| Total operating lease liability                    | \$ 4,748 |
| Less: Current portion of operating lease liability | 1,325    |
| Operating lease liability, less current portion    | \$ 3,423 |

## 9. Warrants

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 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”). 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 connection with the July securities purchase agreement were cancelled. The pre-funded warrants are exercisable immediately 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 and will expire five years from the date of issuance and will have an exercise price of \$3.00 per share. The Series C warrants include certain rights upon “fundamental transactions,” as described in the Series C warrants, including 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 of the unexercised portion of the applicable Series C warrants on the date of the consummation of the fundamental transactions. In October 2024, the pre-funded warrants were fully exercised for de minimis proceeds. As of March 31, 2025, there were 3,333,333 Series C warrants outstanding.

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”). Pursuant to the October Securities Purchase Agreement, the Series A common warrants to purchase an aggregate of 3,246,753 shares of Class A common stock issued were cancelled. The Series B warrants are exercisable following the six-month anniversary of the closing date and will expire five and a half years from the date of issuance and have an exercise price of \$3.08 per share. The Series B warrants include certain rights upon “fundamental transactions,” as described in the Series B warrants, including 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 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 March 31, 2025, there were 3,246,753 Series B warrants outstanding.

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 March 31, 2025, there were 76,336 warrants outstanding.

## 10. Stockholders' Equity

As of March 31, 2025, Rani Holdings held approximately 57% of the Class A Units of Rani LLC, and approximately 43% of the outstanding Class A Units of Rani LLC are held by the Continuing LLC Owners. From the date of the Organizational Transactions to March 31, 2025, 5,318,539 Paired Interests and 315,892 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 three months ended March 31, 2025 and 2024, certain of the Continuing LLC Owners executed an exchange of zero Paired Interests and zero and 83,377 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.

## 11. Stock-Based Compensation

### Stock Options

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

|                               | Number of Stock<br>Option Awards | Weighted<br>Average Exercise<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term (in years) | Aggregate<br>Intrinsic Value<br>(in thousands) |
|-------------------------------|----------------------------------|---------------------------------------|--|--|
| Balance at December 31, 2024  | 10,225,433                       | \$ 5.52                               | 8.18   | \$ —   |
| Granted                       | 1,189,930                        | \$ 1.37                               | 9.97   | \$ —   |
| Canceled                      | (33,682)                         | \$ 7.01                               |  |  |
| Balance at March 31, 2025     | 11,381,681                       | \$ 5.08                               | 8.14   | \$ —   |
| Exercisable at March 31, 2025 | 5,666,542                        | \$ 7.12                               | 7.40   | \$ —   |
| Nonvested at March 31, 2025   | 5,715,139                        | \$ 2.75                               | 8.87   | \$ —   |

As of March 31, 2025, there was \$16.4 million of unrecognized stock-based compensation expense related to stock options which is expected to be recognized over a weighted-average period of approximately 2.5 years.

The Company uses the Black-Scholes option pricing model to estimate the fair value of each stock option award on the date of grant. The assumptions and estimates are as follows:

- *Expected term* - The expected term represents the period of time that stock option awards are expected to remain outstanding. The Company estimates the expected term as the midpoint between actual or expected vesting date and the contractual term.
- *Expected volatility* - The expected volatility was derived from the historical stock volatilities of peer public companies within the Company's industry that are considered to be comparable businesses over a period equivalent to the expected term of the stock option awards, since there has been limited trading history of the Company's stock.
- *Risk-free interest rate* - The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the stock option awards' expected term.
- *Expected dividend yield* - The expected dividend yield is zero as the Company has no plans to make dividend payments.

The following table sets forth the weighted average assumptions used in estimating the fair value of stock option awards on the grant date:

|                          | March 31,<br>2025 |   |
|--------------------------|-------------------|---|
| Expected volatility      | 90.7              | % |
| Risk-free interest rate  | 4.12              | % |
| Expected term (in years) | 5.8               |   |
| Expected dividend yield  | —                 | % |

### ***Restricted Stock Units***

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

|                              | <b>Number of Restricted<br/>Stock Units</b> | <b>Weighted Average Grant-<br/>Date Fair Value per Share</b> |
|------------------------------|---|--|
| Balance at December 31, 2024 | 811,893                                     | \$ 7.08  |
| Vested                       | (156,886)                                   | \$ 9.69  |
| Forfeited                    | (2,138)                                     | \$ 7.62  |
| Balance at March 31, 2025    | 652,869                                     | \$ 6.45  |

As of March 31, 2025, there was \$4.2 million of unrecognized stock-based compensation expense related to RSUs which is expected to be recognized over a weighted-average period of approximately 1.9 years. The total fair value of RSUs vested was \$0.2 million for the three months ended March 31, 2025.

### ***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 (in thousands):

|                                | <b>Three Months Ended March 31,</b> |             |
|--------------------------------|-------------------------------------|-------------|
|                                | <b>2025</b>                         | <b>2024</b> |
| Research and development       | \$ 1,137                            | \$ 1,136    |
| General and administrative     | 2,788                               | 2,734       |
| Total stock-based compensation | \$ 3,925                            | \$ 3,870    |

## **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 March 31, 2025, 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 \$23.3 million at March 31, 2025.

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 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 March 31, 2025, the effective interest rate on the Loans was 14.58% and there were no events of default during the three months ended March 31, 2025. 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 March 31, 2025, the Company was in compliance with all applicable financial covenants under the Loan Agreement.

As of March 31, 2025, future principal payments for the Company’s debt are as follows (in thousands):

|  |           |
|--|-----------|
| Year ending December 31,                   |           |
| 2025 (remaining nine months)               | \$ 11,250 |
| 2026                                       | 10,000    |
| Total principal payments                   | \$ 21,250 |
| Less: amount representing debt discount    | (329)     |
| Total long-term debt                       | \$ 20,921 |
| Less: current portion of long-term debt    | 15,000    |
| Total long-term debt, less current portion | \$ 5,921  |

### 14. Income Taxes

The Company’s effective income tax rate was zero for each of the three months ended March 31, 2025 and 2024. As a result 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 three months ended March 31, 2025 and 2024, 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):

|  | Three Months Ended March 31, |            |
|--|------------------------------|------------|
|  | 2025                         | 2024       |
| <b>Numerator:</b>  |                              |            |
| Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.                   | \$ (7,264)                   | \$ (7,483) |
| <b>Denominator:</b>  |                              |            |
| Weighted average Class A common share outstanding—basic and diluted                                  | 33,440                       | 26,034     |
| Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.—basic and diluted | \$ (0.22)                    | \$ (0.29)  |

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 March 31, |        |
|--------------------------------------|-----------------|--------|
|                                      | 2025            | 2024   |
| Paired Interests                     | 23,972          | 24,116 |
| Stock options                        | 11,382          | 10,348 |
| Warrants                             | 6,656           | 76     |
| Non-corresponding Class A Units      | 1,230           | 1,262  |
| Restricted stock units               | 653             | 1,099  |
| Shares issuable pursuant to the ESPP | 62              | 114    |
| Restricted stock awards              | —               | 26     |
|                                      | 43,955          | 37,041 |

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 three months ended March 31, 2025. Therefore, they are not included in the computation of net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.

## 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, 2024, 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, 2024. Please also see the section titled "Forward Looking Statements."*

*The following discussion contains references to calendar year 2024 and the three months ended March 31, 2025 and 2024, 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, 2024 and the three months ended March 31, 2025 and 2024, 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 have 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 mid-2025.

We believe, the RaniPill capsule technology 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 RaniPill capsule. 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 RaniPill capsule. 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 RaniPill capsule. 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 March 31, 2025, our cash, cash equivalents and marketable securities totaled \$15.9 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 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 from the July Offering were cancelled. The aggregate net proceeds from the October Offering totaled \$9.4 million, after 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, strategic transactions or other arrangements with other companies, or through other sources of financing. If we are not able to obtain additional financing as discussed above, or if we are unable to meet our obligations as they become due, we may need to file a voluntary petition for relief under the United States Bankruptcy Code in order to implement a restructuring plan or liquidation.

#### ***Preclinical Update***

In March 2025, we announced preclinical data demonstrating bioequivalence of RT-114, a bispecific GLP-1/GLP-2 receptor agonist (PG-102) delivered orally via the RaniPill capsule ("RT-114"), to subcutaneously administered PG-102. RT-114 yielded a relative bioavailability of 111% compared to PG-102 delivered subcutaneously with comparable pharmacokinetic profiles and weight loss. RT-114 was well tolerated and was excreted without sequelae in all subjects. Average peak weight loss was the same in both groups with greater variability with subcutaneous dosing ( $6.7\% \pm 0.5\%$  for RT-114 and  $6.7\% \pm 2.2\%$  for subcutaneous PG-102).

In February 2025, we announced preclinical data demonstrating successful oral delivery of the glucagon-like peptide-1 receptor ("GLP-1") agonist semaglutide via the RaniPill HC ("RT-116"). In the study, RT-116 demonstrated comparable bioavailability, pharmacokinetics and weight loss to subcutaneous ("SC") administration of semaglutide. Further, RT-116 was well tolerated with no serious adverse events.



## 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 March 31, 2025 and 2024

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

|   | Three Months Ended March 31, |             |               |
|---|------------------------------|-------------|---------------|
|   | 2025                         | 2024        | Change<br>* % |
| Contract revenue  | \$ 172                       | \$ —        |               |
| Operating expenses  |                              |             |               |
| Research and development                                  | 6,570                        | 7,586       | (13.4)%       |
| General and administrative                                | 5,615                        | 6,448       | (12.9)%       |
| Total operating expenses                                  | \$ 12,185                    | \$ 14,034   | (13.2)%       |
| Loss from operations                                      | (12,013)                     | (14,034)    | (14.4)%       |
| Other income (expense), net                               |                              |             |               |
| Interest income and other, net                            | 218                          | 549         | (60.3)%       |
| Interest expense and other, net                           | (943)                        | (1,294)     | (27.1)%       |
| Net loss  | \$ (12,738)                  | \$ (14,779) | (13.8)%       |
| Net loss attributable to non-controlling interest         | (5,474)                      | (7,296)     | (25.0)%       |
| Net loss attributable to Rani Therapeutics Holdings, Inc. | \$ (7,264)                   | \$ (7,483)  | (2.9)%        |

\*Not meaningful

#### Contract Revenue

Contract revenue of \$0.2 million for the three months ended March 31, 2025, was attributable to evaluation services performed for a customer. There was no contract revenue for the same period in 2024.

#### Research and Development Expenses

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

|  | Three Months Ended March 31, |          |
|--|------------------------------|----------|
|  | 2025                         | 2024     |
| Payroll, stock-based compensation and related benefits | \$ 4,663                     | \$ 5,748 |
| Facilities, materials and supplies                     | 1,415                        | 1,382    |
| Third-party services                                   | 476                          | 443      |
| Other  | 16                           | 13       |
| Total  | \$ 6,570                     | \$ 7,586 |

The decrease of \$1.0 million in research and development expenses in the three months ended March 31, 2025, as compared to the same period in 2024, was primarily attributed to lower compensation costs of \$1.0 million.

#### *General and Administrative Expenses*

The decrease of \$0.8 million in general and administrative expenses in the three months ended March 31, 2025, as compared to the same period in 2024, was primarily attributed to lower compensation costs of \$0.4 million and \$0.5 million reduction in third-party services.

#### *Other Income (Expense), Net*

The change in other income (expense), net, in the three months ended March 31, 2025, as compared to the same period in 2024, was de minimis.

### **Liquidity and Capital Resources**

#### ***Overview***

We have incurred recurring losses and negative cash flows from operations since inception, including net loss of \$12.7 million for three months ended March 31, 2025. As of March 31, 2025, we had an accumulated deficit of \$110.2 million and for three months ended March 31, 2025, had negative cash flows from operations of \$8.1 million. As of March 31, 2025, our cash, cash equivalents and marketable securities totaled \$15.9 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, 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 three months ended March 31, 2025 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 October 2024, we entered into the October Securities Purchase Agreement with an institutional investor relating to the October Offering. The aggregate net proceeds from the October Offering totaled \$9.4 million, after 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. Pursuant to the October Offering, the Series A Warrants were cancelled. In October 2024, the pre-funded warrants were fully exercised for de minimis proceeds.

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 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, 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 which began in September 2024. As of March 31, 2025, we were in compliance with all financial covenants under the Loan Agreement.

In addition, in August 2022, we entered into a Controlled Equity<sup>SM</sup> 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 our 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 ("ATM Sales"). As of March 31, 2025, we had not delivered any placement notices to either of the Agents and there had been no ATM Sales. In May 2025, we and Cantor agreed to terminate Cantor's participation as an Agent under the Sales Agreement. Accordingly, H.C. Wainwright & Co., LLC is now the sole Agent under the Sales Agreement.

Under the rules and regulations of the Securities Act, an issuer with less than \$75 million in public float (outstanding shares of securities listed on a trading market that are held by non-affiliates) may only utilize a Form S-3 registration statement to register securities for sale up to one-third of their public float over a 12-month period. These rules, referred to as “baby shelf” rules, apply to us currently. The baby shelf rules could limit the amount that we raise in a financing or make it more difficult for us to raise financing, including to effect ATM Sales. As a result, for financings that would exceed the limit of securities registrable on Form S-3 under the baby shelf rules, we may be required to issue unregistered securities or to register securities on a Form S-1, which would be expected to require more time, cost and effort than registering securities under a Form S-3.

#### ***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, 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 technology 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 technology 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 technology 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.

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. In the event we determine that additional sources of liquidity will not be available to us or will not allow us to meet our obligations as they become due, we may need to file a voluntary petition for relief under the United States Bankruptcy Code in order to implement a restructuring plan or liquidation.

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

|   | <b>March 31,<br/>2025</b> | <b>December 31,<br/>2024</b> |
|---|---------------------------|------------------------------|
| Cash and cash equivalents                                     | \$ 10,111                 | \$ 3,762                     |
| Marketable securities   | 5,742                     | 23,877                       |
| <b>Total cash, cash equivalents and marketable securities</b> | <b>\$ 15,853</b>          | <b>\$ 27,639</b>             |

As of March 31, 2025, we had cash and cash equivalents and marketable securities of \$15.9 million, compared to \$27.6 million as of December 31, 2024. 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 three months ended March 31, 2025 are issued. Our existing capital resources, will not be sufficient to fund our projected operating requirements for a twelve-month period from the issuance of our financial statements. If we are not able to raise additional funds 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.

#### **Cash Flows**

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

|   | <b>Three Months Ended March 31,<br/>2025</b> | <b>2024</b>     |
|---|--|-----------------|
| Net cash used in operating activities   | \$ (8,149)                                   | \$ (9,402)      |
| Net cash provided by investing activities                                     | 18,229                                       | 10,294          |
| Net cash (used in)/provided by financing activities                           | (3,731)                                      | 121             |
| <b>Net increase in cash, cash equivalents and restricted cash equivalents</b> | <b>\$ 6,349</b>                              | <b>\$ 1,013</b> |

### ***Operating Activities***

Net cash used in operating activities for the three months ended March 31, 2025 was \$8.1 million, which was primarily attributable to a net loss of \$12.7 million and net accretion and amortization of investments in marketable securities of \$0.2 million, partially offset by stock-based compensation expense of \$3.9 million and depreciation and amortization expense of \$0.3 million. Additionally, there was an increase in accounts receivable of \$0.6 million, accounts payable of \$0.2 million, accrued expenses and other current liabilities of \$0.2 million and a decrease in contract asset of \$0.4 million and prepaid expenses and other current assets of \$0.3 million in for the three months ended March 31, 2025.

Net cash used in operating activities for the three months ended March 31, 2024 was \$9.4 million, which was primarily attributable to a net loss of \$14.8 million and net accretion and amortization of investments in marketable securities of \$0.3 million, partially offset by the stock-based compensation expense of \$3.9 million and depreciation and amortization expense of \$0.2 million. Additionally, there was a decrease of \$0.5 million in prepaid expenses and other current assets and an increase in accrued expenses and other current liabilities and accounts payable of \$0.9 million and \$0.2 million for the three months ended March 31, 2024, respectively.

### ***Investing Activities***

For the three months ended March 31, 2025, net cash provided by investing activities was \$18.2 million, which primarily consisted of \$21.0 million in proceeds from maturities of marketable securities partially offset by \$2.7 million in purchases of marketable securities and \$0.1 million in purchases of property and equipment.

For the three months ended March 31, 2024, net cash provided by investing activities was \$10.3 million, which primarily consisted of \$20.4 million in proceeds from maturities of marketable securities partially offset by \$10.0 million in purchases of marketable securities.

### ***Financing Activities***

For the three months ended March 31, 2025, net cash used in financing activities was \$3.7 million, which primarily consisted of repayment of debt of \$3.8 million.

For the three months ended March 31, 2024, net cash provided by financing activities was \$0.1 million in proceeds from the issuance of Class A common stock under the employee stock purchase plan.

### ***Contractual Obligations and Other Commitments***

As of March 31, 2025, 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. 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. 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 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***

None.

## **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 March 31, 2025.

#### **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 March 31, 2025 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 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, 2024.

There is substantial doubt regarding our ability to continue as a going concern and holders of our common stock could suffer a total loss of their investment. We will need to raise additional funding, which may not be available on acceptable terms. If we are unable to raise additional capital when needed, we may be forced to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

Our operations have consumed substantial amounts of cash since our inception. We are in early clinical development with certain product candidates and have conducted or are in preclinical development with other product candidates. To advance our product candidates into initial and later stages of clinical development requires significant capital. In addition, we are developing the RaniPill HC. If the FDA or any comparable foreign regulatory authorities, such as the European Medicines Agency, require that we perform studies or trials in addition to those that we currently anticipate with respect to the development of our product candidates or any of our future product candidates, or repeat studies or trials, our expenses would further increase beyond what we currently expect, and any delay resulting from such further or repeat studies or trials could also result in the need for additional financing.

As of March 31, 2025, our cash, cash equivalents and marketable securities totaled \$15.9 million. Based on our available cash resources and current operating plan, there is substantial doubt regarding our ability to continue as a going concern and holders of our common stock could suffer a total loss of their investment. Our Board of Directors had initiated a review of alternatives, including potential strategic options, and of our financing strategy. Any failure or delay to obtain additional funding could force us to delay, limit or terminate our operations, make reductions in our workforce, liquidate all or a portion of our assets and/or seek protection under Chapter 7 or 11 of the United States Bankruptcy Code. Our existing capital resources 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, including RT-114, and seek regulatory approval thereof, to expand our manufacturing capabilities, and to commercialize any of our product candidates.

Based on our current planned operations, and in the absence of additional sources of liquidity, management anticipates that our existing cash and cash equivalents and anticipated cash flows from operations, will not be sufficient to meet our operating and liquidity needs beyond early August 2025. If we are unable to raise additional funds and 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 audited financial statements, and investors may lose all or a part of their investment.

We may not be able to obtain additional funding on acceptable terms, or at all. As a result of geopolitical events, including the conflicts in Ukraine and Gaza, inflation, rising interest rates and other conditions, the global credit and financial markets have experienced volatility and disruptions. In addition, the report from our independent registered public accounting firm issued in connection with this Annual Report on Form 10-K 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.

If we are unable to obtain funding on a timely basis, or to generate sufficient revenues, if at all, from collaboration arrangements, we may be required to:

- significantly curtail, delay or discontinue one or more of our research or development programs, the development of our oral delivery technology, including the RaniPill HC, the commercialization of any product candidates or cease operations altogether;



- seek collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves;
- forego expansion of our operations or refrain from pursuing business opportunities; or
- file a voluntary petition for relief under the United States Bankruptcy Code in order to implement a restructuring plan or liquidation.

Our efforts to raise additional funding may divert our management from their day-to-day activities, which may adversely affect our ability to develop the RaniPill platform, to progress development of our product candidates or to automate our manufacturing processes.

Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our Class A common stock to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants and other operating restrictions that could adversely impact our ability to conduct our business. The Lender already has a security interest in substantially all of our assets, including our intellectual property, which may prevent or limit our ability to incur additional indebtedness.

Our funding requirements and the timing of our need for additional capital are subject to change based on a number of factors, including:

- the progress, costs, trial design, results and timing of our preclinical studies and clinical trials;
- the progress, costs, and results of our research pipeline;
- the progress and costs of development of the RaniPill HC device and other improvements or advancements to our delivery technologies;
- 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 preclinical studies and clinical trials and other work, as the basis for review and approval of our product candidates;
- 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 capsule;
- our need to expand our research and development activities;
- the costs associated with manufacturing, and obtaining drug supply for, our product candidates, including for clinical and commercial supplies;
- the costs associated with securing and establishing commercial infrastructure, including establishing sales, marketing, and distribution capabilities;
- 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 or enter into strategic transactions;
- 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 and cost-containment measures we propose to implement;
- the economic and other terms, timing of and success of any collaboration, licensing, or other arrangements which we may enter in the future; and
- the effects of disruptions to and volatility in the credit and financial markets in the United States and worldwide from geopolitical conflicts or other such disruptions.

In the event we determine that additional sources of liquidity will not be available to us or will not allow us to meet our obligations as they become due, we may need to file a voluntary petition for relief under the United States Bankruptcy Code in order to implement a restructuring plan or liquidation.

***We do not currently meet the requirements for continued listing on The Nasdaq Global Market. If we fail to meet the requirements for continued listing on The Nasdaq Global Market, trading in our common stock could be suspended and our common stock delisted from Nasdaq, which would have a negative effect on the price of our common stock and our ability to raise additional capital.***

Our Class A common stock is currently listed on The Nasdaq Global Market. We are required to meet specified requirements to maintain our listing on The Nasdaq Global Market, including, among others, a minimum market value of listed securities ("MVLS"), of \$50,000,000 under Nasdaq Listing Rule 5450(b)(2)(A) (the "MVLS Requirement").

On May 1, 2025, we received written notice from the Listing Qualifications Department ("Staff") of The Nasdaq Stock Market LLC ("Nasdaq") notifying us that we were not in compliance with the MVLS Requirement (the "Notice"). In accordance with the Nasdaq Listing Rules, we were granted 180 calendar days, or until October 28, 2025, to regain compliance with the MVLS Requirement. In order to do so, we must achieve and maintain an MVLS of at least \$50,000,000 or more for a minimum of 10 consecutive business days. If we do not regain compliance with the MVLS Requirement by October 28, 2025, the Notice states that we will receive written notification that our securities are subject to delisting. At that time, we may appeal the delisting determination to a Nasdaq hearings panel. Alternatively, we may apply for a transfer of the listing of its securities to The Nasdaq Capital Market, provided that we then meet the continued listing requirements on The Nasdaq Capital Market. We are considering actions that we may take in response to the Notice to regain compliance with the continued listing requirements, but no decisions about a response have been made at this time. There can be no assurance that we will be able to regain compliance with the MVLS requirement or will otherwise be in compliance with other Nasdaq listing criteria. For example, Nasdaq Listing Rule 5450(a)(1) requires listed securities to maintain a minimum bid price of \$1.00 per share (the "Minimum Bid Price Requirement") and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the Minimum Bid Price Requirement exists if the deficiency continues for a period of 30 consecutive trading days. The per share price of our common stock has fluctuated significantly and has traded below \$1.00 per share for the past 5 consecutive trading days. Our stock price may not close at or above \$1.00 per share and if the price remains below \$1.00 per share for a period of 30 consecutive trading days, our stock could become subject to delisting because of the failure to satisfy the Minimum Bid Price Requirement.

The delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and would also make it more difficult for our stockholders to sell or purchase our common stock when they wish to do so. If delisted from The Nasdaq Global Market, and not able to transfer to The Nasdaq Capital Market, we will likely trade on the OTC Markets system, which could make it more difficult to dispose of, or obtain accurate quotations for the price of, our common stock, and may lead to a reduction in coverage by securities analysts and the news media, which could cause the price of our common stock to decline further.

***International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.***

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States, including suppliers of drug substance for our pipeline programs and suppliers of certain raw materials for the manufacture of the RaniPill® capsule. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

We manufacture the RaniPill® capsule in the United States. We are vertically integrated and manufacture many of the components used in the RaniPill® capsule. We source raw materials for our components and manufacturing from a variety of suppliers. Currently, nearly all of the principal suppliers of our raw materials and externally-sourced components used to support our manufacturing come from suppliers located in the United States. The current principal supplier of one raw material is located in China. We obtain supply of the drug substances used for our pipeline programs from third parties. The drug substance for our RT-114 (bispecific GLP-1/GLP-2 receptor agonist) program is manufactured in Korea and China, and the drug substances for our RT-111 (ustekinumab biosimilar) and RT-105 (adalimumab biosimilar) programs are manufactured in Korea. The drug substance for our RT-102 (parathyroid hormone) and RT-110 programs is manufactured in the United States.

Current or future tariffs will result in increased research and development and manufacturing expenses, including with respect to increased costs associated with drug substances, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing or collaborations on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our collaborators or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, collaborators and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have heightened and may continue to heighten the risks related to the other risk factors described in our Annual Report for the fiscal year ended December 31, 2024.

## **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            | <a href="#"><u>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).</u></a> |
| 3.2            | <a href="#"><u>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).</u></a>                        |
| 31.1*          | <a href="#"><u>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.</u></a>  |
| 31.2*          | <a href="#"><u>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.</u></a>  |
| 32.1*†         | <a href="#"><u>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.</u></a>   |
| 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: May 13, 2025

By: /s/ Talat Imran  
**Talat Imran**  
*Chief Executive Officer*  
*(Principal Executive Officer)*

Date: May 13, 2025

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

**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: May 13, 2025

/s/ Talat Imran

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Talat Imran

Chief Executive Officer

*(Principal Executive Officer)*

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**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: May 13, 2025

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

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**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 March 31, 2025, 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: May 13, 2025

**IN WITNESS WHEREOF**, the undersigned have set their hands hereto as of the 13th day of May, 2025

/s/ Talat Imran  
Talat Imran  
Chief Executive Officer  
(Principal Executive Officer)

/s/ Svai Sanford  
Svai Sanford  
Chief Financial 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.

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