

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 06, 2024

Rani Therapeutics Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40672
(Commission File Number)

86-3114789
(IRS Employer
Identification No.)

2051 Ringwood Avenue
San Jose, California
(Address of principal executive offices)

95131
(Zip Code)

Registrant's Telephone Number, Including Area Code: (408) 457-3700

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition.

On May 6, 2024, Rani Therapeutics Holdings, Inc. (the “Company”) issued a press release providing a corporate update and announcing its financial results for the three months ended March 31, 2024. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

Exhibit Number	Exhibit Description
99.1	Press Release of Rani Therapeutics Holdings, Inc. dated May 6, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 6, 2024

By: /s/ Svai Sanford
Svai Sanford
Chief Financial Officer



Rani Therapeutics Reports First Quarter 2024 Financial Results; Provides Corporate Update

- *Announced Positive Topline Results from Phase 1 Study of an Oral Anti-Interleukin 12/23 Antibody (RT-111) -*
- *Initiation of Phase 2 clinical trial for RT-102 for the treatment of osteoporosis expected in 2024 –*
- *RaniPill HC to be ready for potential Phase 1 clinical trials in the second half of 2024 -*

SAN JOSE, Calif., May 6, 2024 --Rani Therapeutics Holdings, Inc. (“Rani Therapeutics” or “Rani”) (Nasdaq: RANI), a clinical-stage biotherapeutics company focused on the oral delivery of biologics and drugs, today reported financial results for the quarter ended March 31, 2024 and provided a corporate update.

“We are pleased with the progress we have made in the first quarter having announced positive topline results from our Phase 1 study for RT-111. We believe that RT-111 could have a favorable product profile and a differentiated dosing regimen in the competitive landscape for autoimmune disorders,” said Talat Imran, Chief Executive Officer of Rani. “Furthermore, the RaniPill platform has the potential to combine the efficacy, specificity, and long half-life of a monoclonal antibody with the convenience and dosing flexibility of a pill to create products that are attractive to both patients and physicians across a wide array of therapeutic areas. We look forward to providing updates throughout the year as we make progress on our programs and continue to evaluate opportunities for Rani to deliver upon its mission to end painful injections for the millions of patients suffering from chronic diseases.”

First Quarter 2024 and Subsequent Highlights:

- **Announced Positive Topline Results from Phase 1 Study of an Oral Anti-Interleukin 12/23 Antibody (RT-111).** In February 2024, Rani announced RT-111 achieved high bioavailability and was well-tolerated, with no serious adverse events in humans in a Phase 1 study. The ustekinumab biosimilar used in RT-111 is manufactured and supplied by Celltrion, Inc. Celltrion has right of first negotiation to acquire worldwide rights to RT-111 following a Phase 1 clinical trial that meets its primary endpoints.

Near-Term Milestone Expectations:

- Initiation of Phase 2 clinical trial of RT-102, a RaniPill capsule containing teriparatide for osteoporosis, in 2024.
- Development of RaniPill HC to be ready for potential Phase 1 clinical trials in the second half of 2024.

First Quarter 2024 Financial Results:

- **Cash, cash equivalents and marketable securities** as of March 31, 2024 totaled \$39.6 million, compared to \$48.5 million for the year ended December 31, 2023.
 - **Research and development expenses** for the three months ended March 31, 2024 were \$7.6 million, compared to \$9.7 million for the same period in 2023. The decrease of \$2.1 million was primarily attributed to lower compensation costs of \$1.6 million due to reduction in workforce and \$0.4 million reduction in third-party service costs.
 - **General and administrative expenses** for the three months ended March 31, 2024 were \$6.4 million, compared to \$6.8 million for the same period in 2023. The decrease of \$0.4 million was primarily attributed to lower compensation costs of \$0.2 million due to reduction in workforce and \$0.2 million reduction in other costs.
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- **Net loss** for the three months ended March 31, 2024 was \$14.8 million, compared to \$16.8 million for the same period in 2023, including stock-based compensation expense of \$3.9 million for the three months ended March 31, 2024, compared to \$4.4 million for the same period in 2023.

About Rani Therapeutics

Rani Therapeutics is a clinical-stage biotherapeutics company focused on advancing technologies to enable the development of orally administered biologics and drugs. Rani has developed the RaniPill capsule, which is a novel, proprietary and patented platform technology, intended to replace subcutaneous injection or intravenous infusion of biologics and drugs with oral dosing. Rani has successfully conducted several preclinical and clinical studies to evaluate safety, tolerability and bioavailability using RaniPill capsule technology. For more information, visit ranitherapeutics.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the expected initiation of a Phase 2 trial of RT-102 in 2024, the expected readiness of the RaniPill HC for clinical development in the second half of 2024, Rani’s development and advancement of its RaniPill capsule technology, including RaniPill HC, Rani’s advancement of its preclinical and clinical programs and timing of results, the potential of RaniPill products to have attractive product profiles, the sufficiency of Rani’s cash reserves, the timing and extent of its expenses, future financial performance, and Rani’s growth as a company. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as “could,” “look forward,” “potential,” “believe,” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Rani’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with Rani’s business in general and the other risks described in Rani’s filings with the Securities and Exchange Commission, including Rani’s annual report on Form 10-K for the year ended December 31, 2023 and subsequent filings and reports by Rani. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management’s assumptions and estimates as of such date. Rani undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

Trademarks

Trade names, trademarks and service marks of other companies appearing in this press release are the property of their respective owners. Solely for convenience, the trademarks and trade names referred to in this press release appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

Investor Contact:

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Media Contact:

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RANI THERAPEUTICS HOLDINGS, INC
Consolidated Balance Sheets
(In thousands, except par value)

	<u>March 31,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u>
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 6,877	\$ 5,864
Marketable securities	32,704	42,675
Prepaid expenses and other current assets	1,809	2,308
Total current assets	41,390	50,847
Property and equipment, net	5,905	6,105
Operating lease right-of-use asset	5,971	718
Other assets	246	246
Total assets	\$ 53,512	\$ 57,916
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 806	\$ 648
Accrued expenses and other current liabilities	2,761	1,726
Current portion of long-term debt	8,586	4,897
Current portion of operating lease liability	1,222	718
Total current liabilities	13,375	7,989
Long-term debt, less current portion	20,853	24,484
Operating lease liability, less current portion	4,749	—
Total liabilities	38,977	32,473
Stockholders' equity:		
Preferred stock, \$0.0001 par value - 20,000 shares authorized; none issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Class A common stock, \$0.0001 par value - 800,000 shares authorized; 26,294 and 26,036 issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	3	3
Class B common stock, \$0.0001 par value - 40,000 shares authorized; 24,116 issued and outstanding as of March 31, 2024 and December 31, 2023	2	2
Class C common stock, \$0.0001 par value - 20,000 shares authorized; none issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Additional paid-in capital	87,776	85,762
Accumulated other comprehensive loss	(11)	(12)
Accumulated deficit	(80,372)	(72,889)
Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc.	7,398	12,866
Non-controlling interest	7,137	12,577
Total stockholders' equity	14,535	25,443
Total liabilities and stockholders' equity	\$ 53,512	\$ 57,916

RANI THERAPEUTICS HOLDINGS, INC
Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Operating expenses		
Research and development	\$ 7,586	\$ 9,712
General and administrative	6,448	6,804
Total operating expenses	\$ 14,034	\$ 16,516
Loss from operations	(14,034)	(16,516)
Other income (expense), net		
Interest income and other, net	549	891
Interest expense and other, net	(1,294)	(1,207)
Net loss	\$ (14,779)	\$ (16,832)
Net loss attributable to non-controlling interest	(7,296)	(8,460)
Net loss attributable to Rani Therapeutics Holdings, Inc.	\$ (7,483)	\$ (8,372)
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted	\$ (0.29)	\$ (0.33)
Weighted-average Class A common shares outstanding—basic and diluted	26,034	25,240

