

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): March 20, 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 March 20, 2024, Rani Therapeutics Holdings, Inc. (the “Company”) issued a press release providing a corporate update and announcing its financial results for the fourth quarter and year ended December 31, 2023. 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**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
99.1	<a href="#">Press Release of Rani Therapeutics Holdings, Inc. dated March 20, 2024</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: March 20, 2024

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

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## Rani Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results; Provides Corporate Update

- Announced Positive Topline Results from Phase 1 Study of an Oral Anti-Interleukin 12/23 Antibody (RT-111) -

- Announced Preclinical Pharmacodynamic Data on Transenteric Delivery of GLP-1 Incretin Triagonist -

- Cash runway extended into 2025 -

- Conference call and webcast today at 4:30 p.m. ET / 1:30 p.m. PT -

**SAN JOSE, Calif., March 20, 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 and full year ended December 31, 2023 and provided a corporate update.

"We have kicked off 2024 with positive momentum announcing positive topline results from our Phase 1 study for RT-111, which serves as our third successfully completed Phase 1 trial using RaniPill technology," said Talat Imran, Chief Executive Officer of Rani. "The results of our Phase 1 study for RT-111 provide validation that our platform can transform injectable large molecules into convenient, oral pills. We are committed to our vision of making oral biologics a reality across a wide variety of indications. Looking ahead, we continue development of the RaniPill HC to be ready for potential Phase 1 clinical trials in the second half of the year."

### Fourth Quarter 2023 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.
- **Announced Preclinical Pharmacodynamic Data on Transenteric Delivery of GLP-1 Incretin Triagonist.** In December 2023, Rani announced preclinical data demonstrating the transenteric delivery of an incretin triagonist of GLP-1, GIP, glucagon receptors elicits rapid weight loss in animal study. Preclinical data support the potential for the RaniPill platform to enable oral delivery of multiple obesity treatments.
- **Announced Strategic Program Prioritization, Expansion of Manufacturing and Plans to Streamline Business Operations to Support Near-Term Value Drivers and Long-Term Growth of the RaniPill Technology Platform.** In November 2023, Rani announced strategic prioritization of its key development programs, RT-102, RT-111 and the RaniPill HC and expansion of its manufacturing footprint to support increased scale and partnerships, and cost reduction initiatives that align with Rani's near-term goals. Development of RT-101 was discontinued, while the development of RT-105 and RT-110 programs were paused. In addition, Rani reduced its workforce. Anticipated cost savings are expected to support Rani's operating plans into 2025.
- **Completed 60-Day, Repeat Oral-Administration GLP Safety Study.** In October 2023, Rani announced preclinical data from a 60-day, repeat oral-administration GLP safety study of the RaniPill capsule in healthy animals. The RaniPill capsule was well-tolerated with no treatment-related adverse events and all animals remained clinically healthy throughout the study.
- **Announced Successful Oral Delivery of Humira® (adalimumab) via High-Capacity Pill in Preclinical Study.** In October 2023, Rani announced the successful oral delivery of a monoclonal antibody, Humira® (adalimumab), via its high-capacity capsule, the RaniPill HC, in a preclinical study. The preclinical study tracked the serum concentrations of adalimumab, following the oral administration of the enteric-coated,

RaniPill HC capsule containing 11mg of Humira® (adalimumab) to four canine models. The RaniPill HC successfully delivered adalimumab in all of the subjects.

- **Presented an Abstract on RT-102 at the 2023 Annual Meeting of the American Society for Bone and Mineral Research.** The abstract, presented in October 2023, focused on the safe and reliable delivery of teriparatide with high bioavailability through daily administration of an oral robotic pill (RT-102) in female volunteers.

#### **Near-Term Milestone Expectations:**

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

#### **Full Year 2023 Financial Results:**

- **Cash, cash equivalents and marketable securities** as of December 31, 2023 totaled \$48.5 million, compared to \$98.5 million for the year ended December 31, 2022.
- **Research and development expenses** for the three and twelve months ended December 31, 2023 were \$7.6 million and \$39.6 million, respectively, compared to \$10.4 million and \$36.6 million for the same periods in 2022, respectively. The year over year increase of \$3.0 million was primarily attributed to higher compensation costs of \$1.4 million, an increase of \$1.2 million in third-party services and an increase of \$0.6 million in facilities, materials and supplies expense related to preclinical and clinical development activities, offset by a decrease in other costs of \$0.2 million.
- **General and administrative expenses** for the three and twelve months ended December 31, 2023 were \$5.8 million and \$26.5 million, respectively, compared to \$7.1 million and \$26.8 million for the same periods in 2022, respectively. The year over year decrease of \$0.3 million was primarily attributed to lower third-party services of \$1.8 million related to support for compliance with public company requirements and lower facilities, material and supplies and other costs of \$0.3 million, offset by higher compensation costs of \$1.8 million.
- **Net loss** for the three and twelve months ended December 31, 2023 was \$14.1 million and \$67.9 million, respectively, compared to \$17.3 million and \$63.3 million for the same periods in 2022, respectively, including stock-based compensation expense of \$4.5 million for the three months ended December 31, 2023 and \$19.0 million for the full year 2023, compared to \$4.5 million and \$15.8 million for the same periods in 2022, respectively.

#### **Conference Call**

Rani will host a corresponding conference call and live webcast at 4:30 p.m. ET / 1:30 p.m. PT on March 20, 2024 to discuss the results and provide a business update. Individuals interested in listening to the live conference call may do so by using the webcast link in the “Investors” section of the company’s website at [www.ranitherapeutics.com](http://www.ranitherapeutics.com). A webcast replay will be available in the investor relations section on the company’s website for 90 days following the completion of the call.

#### **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](http://ranitherapeutics.com).

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## **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, the ability of expanded manufacturing footprint to support scaling of manufacturing and partnering, the ability to streamline its business operations and to realize the cost-savings contemplated by such streamlining of business operations, reduction in workforce and other initiatives announced by Rani, 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 sufficiency of Rani’s cash reserves to support operations into 2025, 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 “expect,” “could,” “anticipate,” “look forward,” “potential,” “intend” 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)

	December 31,	
	2023	2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 5,864	\$ 27,007
Marketable securities	42,675	71,475
Prepaid expenses and other current assets	2,308	2,442
Total current assets	50,847	100,924
Property and equipment, net	6,105	6,038
Operating lease right-of-use asset	718	1,065
Other assets	246	—
Total assets	\$ 57,916	\$ 108,027
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 648	\$ 1,460
Accrued expenses and other current liabilities	1,726	2,349
Current portion of long-term debt	4,897	—
Current portion of operating lease liability	718	1,006
Total current liabilities	7,989	4,815
Long-term debt, less current portion	24,484	29,149
Operating lease liability, less current portion	—	59
Total liabilities	32,473	34,023
Stockholders' equity:		
Preferred stock, \$0.0001 par value - 20,000 shares authorized; none issued and outstanding as of December 31, 2023 and December 31, 2022	—	—
Class A common stock, \$0.0001 par value - 800,000 shares authorized; 26,036 and 25,295 issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	3	3
Class B common stock, \$0.0001 par value - 40,000 shares authorized; 24,116 issued and outstanding as of December 31, 2023 and December 31, 2022	2	2
Class C common stock, \$0.0001 par value - 20,000 shares authorized; none issued and outstanding as of December 31, 2023 and December 31, 2022	—	—
Additional paid-in capital	85,762	75,842
Accumulated other comprehensive loss	(12)	(73)
Accumulated deficit	(72,889)	(38,919)
Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc.	12,866	36,855
Non-controlling interest	12,577	37,149
Total stockholders' equity	25,443	74,004
Total liabilities and stockholders' equity	\$ 57,916	\$ 108,027

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

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Operating expenses				
Research and development	\$ 7,606	\$ 10,386	\$ 39,624	\$ 36,607
General and administrative	5,829	7,097	26,475	26,844
Total operating expenses	<u>\$ 13,435</u>	<u>\$ 17,483</u>	<u>\$ 66,099</u>	<u>\$ 63,451</u>
Loss from operations	(13,435)	(17,483)	(66,099)	(63,451)
Other income (expense), net				
Interest income and other, net	676	818	3,301	1,248
Interest expense and other, net	(1,296)	(719)	(5,085)	(1,071)
Loss before income taxes	(14,055)	(17,384)	(67,883)	(63,274)
Income tax expense	—	41	—	(70)
Net loss	<u>\$ (14,055)</u>	<u>\$ (17,343)</u>	<u>\$ (67,883)</u>	<u>\$ (63,344)</u>
Net loss attributable to non-controlling interest	(6,956)	(8,556)	(33,913)	(32,756)
Net loss attributable to Rani Therapeutics Holdings, Inc.	<u>\$ (7,099)</u>	<u>\$ (8,787)</u>	<u>\$ (33,970)</u>	<u>\$ (30,588)</u>
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted	<u>\$ (0.27)</u>	<u>\$ (0.35)</u>	<u>\$ (1.33)</u>	<u>\$ (1.28)</u>
Weighted-average Class A common shares outstanding—basic and diluted	<u>25,874</u>	<u>24,910</u>	<u>25,505</u>	<u>23,817</u>



