

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): August 11, 2023

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 August 11, 2023, Rani Therapeutics Holdings, Inc. (the “Company”) issued a press release providing a corporate update and announcing its financial results for the second quarter ended June 30, 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 dated August 11, 2023</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: August 11, 2023

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

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### **Rani Therapeutics Reports Second Quarter 2023 Financial Results; Provides Corporate Update**

*- Expansion of partnership with Celltrion for development of RT-105 to complement existing partnership for RT-111*

*- Appointment of Kate McKinley as Chief Business Officer*

*- Presentation of three abstracts on RT-102 and RT-112 at the Endocrine Society Annual Conference and selection as winner of Presidential Poster Competition in its category for exceptional scientific work on RT-102*

*- Presentation of late-breaking abstract on oral delivery of GLP-1 agonist at American Diabetes Association's Scientific Sessions*

*- Plan to initiate Phase 2 study for RT-102 and Phase 1 study for RT-111 in 2H of 2023*

**SAN JOSE, Calif., August 11, 2023** -- 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 June 30, 2023, and provided a corporate update.

"We are thrilled to have the opportunity to build upon our existing partnership with Celltrion," said Talat Imran, Chief Executive Officer of Rani. "The partnership to develop RT-105 is our first involving the RaniPill<sup>®</sup>HC, a high-capacity device that is designed to deliver up to a 500%-plus higher drug payload than Rani's existing oral biologics capsule. Looking ahead, we anticipate a productive second half of the year including initiation of a Phase 2 study for RT-102 and a Phase 1 study for RT-111, our first clinical study with a monoclonal antibody."

#### **Second Quarter or Subsequent Highlights:**

- **Announced expansion of partnership with Celltrion to include adalimumab biosimilar for RT-105.** This is the second deal announced between Rani and Celltrion, building upon a previously announced partnership for ustekinumab biosimilar for RT-111. Under the terms of the new license and supply agreement announced in June 2023, Celltrion will exclusively supply to Rani the adalimumab biosimilar drug substance (CT-P17) required for RT-105. Rani is granted an exclusive license to use CT-P17 in the development and commercialization of RT-105, and Celltrion is granted a right of first negotiation to acquire worldwide rights to RT-105 following a Phase 1 study.
  - **Appointed Kate McKinley as Chief Business Officer.** In May 2023, Ms. McKinley joined Rani's executive leadership team bringing with her 20 years of biopharmaceutical industry experience. She has proven success in securing global partnerships and executing regulatory and commercial strategies with respect to biologics, cell therapies and small molecules across multiple therapeutic areas.
  - **Presented three abstracts at Endocrine Society Annual Conference (ENDO).** Rani presented two abstracts on RT-102, an orally administered version of human parathyroid hormone analog teriparatide, which is being developed as an osteoanabolic therapy for osteoporosis. Both abstracts were nominated for ENDO's Presidential Poster Competition and one of which was named the winner of the competition in the area of Bone and Mineral Metabolism. The Endocrine Society committee recognized Rani for its exceptional scientific work on RT-102. Rani presented a third abstract on an orally administered, follicle-stimulating hormone biosimilar and patient preference which reported that a vast majority (91%) of patients surveyed preferred an oral pill over parenteral injection.
  - **Presented late-breaking abstract on the oral delivery of GLP-1 agonist at the American Diabetes Association Annual Conference (ADA).** The abstract focused on the oral delivery of a GLP-1 agonist with high bioavailability in dogs and humans.
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### Near-Term Milestone Expectations:

- Initiation of Phase 2 study of RT-102 for osteoporosis expected in the second half of 2023
- Initiation of Phase 1 study of RT-111 containing an ustekinumab biosimilar in the second half of 2023

### Second Quarter Financial Results:

- **Cash, cash equivalents and marketable securities** as of June 30, 2023, totaled \$74.6 million, compared to cash, cash equivalents and marketable securities of \$98.5 million for the year ended December 31, 2022. Rani expects its cash, cash equivalents and marketable securities to be sufficient to fund its operations through at least the next twelve months.
- **Research and development expenses** for the three months ended June 30, 2023, were \$11.1 million, compared to \$9.5 million for the same period in 2022. The increase was primarily attributed to higher compensation costs of \$1.4 million, which includes an increase of \$0.2 million in stock-based compensation, due to headcount growth.
- **General and administrative expenses** for the three months ended June 30, 2023, were \$7.2 million, compared to \$6.3 million for the same period in 2022. The increase was primarily attributed to higher compensation costs of \$1.2 million, which includes an increase of \$0.9 million in stock-based compensation, due to headcount growth, partially offset by a decrease in third-party services of \$0.3 million due to non-recurring public company-related costs.
- **Net loss** for the three months ended June 30, 2023, was \$18.7 million, compared to \$16.0 million for the same period in 2022, including non-cash charges primarily attributed to stock-based compensation expense of \$4.8 million for the three months ended June 30, 2023, compared to \$4.1 million for the same period in 2022.

### 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<sup>®</sup> 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 is progressing two RaniPill<sup>®</sup> capsules, the RaniPill<sup>®</sup>GO and the RaniPill<sup>®</sup>HC. 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 potential for the partnerships with Celltrion to deliver value, the advancement of Rani’s pipeline and RaniPill® platform technology including the RaniPill®HC, the potential of the RaniPill®HC to deliver 500%-plus higher drug payload than Rani’s existing oral biologics capsule or drug, the expected initiation of a Phase 2 trial of RT-102 and a Phase 1 trial of RT-111 in 2023, the ability to confirm preliminary reliability and optimize performance of the RaniPill®HC, the market opportunity for Rani utilizing the RaniPill®HC, customer acceptance of the RaniPill® capsule technology, the potential benefits of the RaniPill® capsule technology, cash sufficiency forecast, 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 “continue,” “potential,” “designed,” “confirm,” “anticipate,” “plan” 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, 2022, 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.

## **Investor Contact:**

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## **Media Contact:**

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

	<u>June 30,</u> <u>2023</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2022</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 7,552	\$ 27,007
Marketable securities	67,054	71,475
Prepaid expenses and other current assets	1,768	2,442
Total current assets	76,374	100,924
Property and equipment, net	5,939	6,038
Operating lease right-of-use asset	1,194	1,065
Total assets	<u>\$ 83,507</u>	<u>\$ 108,027</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,037	\$ 1,460
Accrued expenses and other current liabilities	3,842	2,349
Operating lease liability, current portion	856	1,006
Total current liabilities	5,735	4,815
Operating lease liability, less current portion	338	59
Long-term debt	29,265	29,149
Total liabilities	35,338	34,023
Stockholders' equity:		
Preferred stock, \$0.0001 par value - 20,000 shares authorized; none issued and outstanding as of June 30, 2023 and December 31, 2022	—	—
Class A common stock, \$0.0001 par value - 800,000 shares authorized; 25,517 and 25,295 issued and outstanding as of June 30, 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 June 30, 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 June 30, 2023 and December 31, 2022	—	—
Additional paid-in capital	80,746	75,842
Accumulated other comprehensive loss	(63)	(73)
Accumulated deficit	(56,594)	(38,919)
Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc.	24,094	36,855
Non-controlling interest	24,075	37,149
Total stockholders' equity	48,169	74,004
Total liabilities and stockholders' equity	<u>\$ 83,507</u>	<u>\$ 108,027</u>



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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	11,086	9,528	\$ 20,798	\$ 17,118
General and administrative	7,208	6,319	14,012	12,509
Total operating expenses	\$ 18,294	\$ 15,847	\$ 34,810	\$ 29,627
Loss from operations	(18,294)	(15,847)	(34,810)	(29,627)
Other income (expense), net				
Interest income and other, net	896	35	1,787	50
Interest expense and other, net	(1,266)	—	(2,473)	—
Loss before income taxes	(18,664)	(15,812)	(35,496)	(29,577)
Income tax expense	—	(154)	—	(217)
Net loss	\$ (18,664)	\$ (15,966)	\$ (35,496)	\$ (29,794)
Net loss attributable to non-controlling interest	(9,361)	(8,342)	(17,821)	(15,947)
Net loss attributable to Rani Therapeutics Holdings, Inc.	\$ (9,303)	\$ (7,624)	\$ (17,675)	\$ (13,847)
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted	\$ (0.37)	\$ (0.31)	\$ (0.70)	\$ (0.60)
Weighted-average Class A common shares outstanding—basic and diluted	25,345	24,371	25,293	22,930

