

**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 11, 2022**

**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
<b>Class A common stock, par value \$0.0001 per share</b>	<b>RANI</b>	<b>The Nasdaq Stock Market LLC</b>

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.

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**Item 2.02 Results of Operations and Financial Condition.**

On May 11, 2022, Rani Therapeutics Holdings, Inc. (the “Company”) issued a press release providing a corporate update and announcing its financial results for the first quarter of the year ending December 31, 2022. 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**

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	<a href="#">Press Release dated May 11, 2022.</a>
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 hereunto duly authorized.

**Rani Therapeutics Holdings, Inc.**

Date: May 11, 2022

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



**Rani Therapeutics Reports First Quarter 2022 Financial Results; Provides Corporate Update**

- *Initiated a Phase 1 clinical trial of RT-102 for the treatment of osteoporosis –*
- *Unveiled the high-capacity RaniPill™ HC, capable of delivering payloads of up to 20 mg –*
- *Strengthened Board with the appointment of Lisa Rometty -*

**SAN JOSE, Calif., May 11, 2022** — Rani Therapeutics Holdings, Inc. (“Rani Therapeutics” or “Rani”) (Nasdaq: RANI), a clinical-stage biotherapeutics company focused on the oral delivery of biologics, today reported financial results for the first quarter ended March 31, 2022 and provided a corporate update.

“We started the year off strong, having unveiled the high-capacity RaniPill HC, advanced RT-102 into the clinic for a Phase 1 trial in osteoporosis, and continued development of our pipeline,” said Talat Imran, Chief Executive Officer of Rani Therapeutics. “I am delighted with the announcement of the RaniPill HC and look forward to exploring the opportunities it provides in expanding Rani’s pipeline and positioning the company for additional partnerships. Looking to our clinical trials, we expect to provide an update on our ongoing Phase 1 study of RT-102 for osteoporosis and initiate Rani’s third Phase 1 clinical trial, in the second half of the year.”

**First Quarter Highlights**

- **Initiated a Phase 1 Clinical Study of RT-102.** In March 2022, Rani announced the initiation of a Phase 1 clinical study of RT-102, a RaniPill capsule containing parathyroid hormone for the treatment of osteoporosis, in Australia. The single-center, open label, Phase 1 study is evaluating the pharmacokinetics, safety and tolerability of RT-102 administered in healthy adult women volunteers. Preclinical data of RT-102 demonstrated a pharmacokinetic profile comparable to published data for once-daily PTH injections for the treatment of osteoporosis.
- **Unveiled the RaniPill High Capacity (HC).** In February 2022, Rani announced the development of the RaniPill HC, an oral device capable of delivering therapeutic payloads of up to 500%-plus more than the original RaniPill capsule. In preclinical testing in a canine model using an adalimumab payload, the RaniPill HC deployed successfully and yielded a PK profile proportional to historical data obtained with adalimumab delivered via the original RaniPill capsule.
- **Appointed Lisa Rometty to Board of Directors.** In January 2022, Rani appointed Lisa Rometty to its Board of Directors. Ms. Rometty has more than two decades of global commercialization and product development experience in the biotechnology and healthcare space.

**Expected Near-Term Milestones**

- Topline Phase 1 RT-102 data readout expected in 2H 2022
- Initiation of an additional Phase 1 clinical trial expected in 2H 2022

## First Quarter Financial Results

- **Cash and cash equivalents** as of March 31, 2022 were \$107.8 million, compared to \$117.4 million as of December 31, 2021. Rani expects its cash and cash equivalents balance to be sufficient to fund its operating expenses and capital expenditure requirements at least until the end of 2023.
- **Research and development expenses** for the three months ended March 31, 2022 were \$7.6 million, compared to \$3.3 million for the same period in 2021. The increase was primarily attributed to higher compensation and benefits due to the increase in headcount, including \$1.2 million of non-cash equity-based compensation expense, initiation of a Phase 1 clinical trial, and ongoing development of the RaniPill HC.
- **General and administrative expenses** for the three months ended March 31, 2022 were \$6.2 million, compared to \$2.6 million for the same period in 2021. The increase was primarily attributed to the public company related costs and higher compensation and benefits due to the increase in headcount, including \$1.7 million of non-cash equity-based compensation expense.
- **Net loss** for the three months ended March 31, 2022 was \$13.8 million, compared to \$5.6 million for the same period in 2021.

## Rani Therapeutics

Rani Therapeutics is a clinical stage biotherapeutics company focused on advancing technologies to enable the development of orally administered biologics. Rani has developed RaniPill capsules, which are a novel, proprietary and patented platform technology, intended to replace subcutaneous injection or intravenous infusion of biologics with oral dosing. Rani has successfully conducted several preclinical and clinical studies to evaluate safety, tolerability and bioavailability using RaniPill capsules. For more information, visit [ranitherapeutics.com](http://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 timing of topline results from Rani’s Phase 1 trial of RT-102, the expected initiation of an additional Phase 1 trial of another product candidate in the second half of 2022, expected progress with the RaniPill HC platform, and potential expansion of Rani’s prospective opportunity, alone or in partnership, to an additional 50 biologics across multiple new indications, Rani’s development and advancement of its RaniPill capsule technology, including RaniPill HC, the impact of its technology on medical treatment, Rani’s advancement of its preclinical and clinical programs and timing of results, customer acceptance of the RaniPill capsule technology, the potential benefits of the RaniPill capsule technology, Rani’s ability to attract and retain talent, Rani’s prospects for entering into strategic partnerships or transactions, and Rani’s growth as a company. Because such statements are subject to risks and uncertainties, actual results may differ

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materially from those expressed or implied by such forward-looking statements. Words such as “may,” “expect,” “could,” “anticipate,” “look forward,” “progress,” “advance” 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, the impact of the COVID-19 pandemic, and the other risks described in Rani’s filings with the Securities and Exchange Commission. 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.

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

	<u>March 31,</u> <u>2022</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2021</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 107,839	\$ 117,453
Prepaid expenses	1,421	2,142
Total current assets	109,260	119,595
Property and equipment, net	4,890	4,612
Operating lease right-of-use asset	1,159	—
Total assets	<u>\$ 115,309</u>	<u>\$ 124,207</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,265	\$ 1,080
Related party payable	140	126
Accrued expenses	2,101	1,434
Operating lease liability, current portion	650	—
Total current liabilities	4,156	2,640
Operating lease liability, net current portion	509	—
Total liabilities	4,665	2,640
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value—20,000 shares authorized; none issued and outstanding as of March 31, 2022 and December 31, 2021	—	—
Class A common stock, \$0.0001 par value—800,000 shares authorized; 24,387 and 19,712 issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	2	2
Class B common stock, \$0.0001 par value—40,000 shares authorized; 24,773 and 29,290 issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	3	3
Class C common stock, \$0.0001 par value—20,000 shares authorized; none issued and outstanding as of March 31, 2022 and December 31, 2021	—	—
Additional paid-in capital	67,933	55,737
Accumulated deficit	(14,554)	(8,331)
Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc.	53,384	47,411
Non-controlling interest	57,260	74,156
Total stockholders' equity	110,644	121,567
Total liabilities and stockholders' equity	<u>\$ 115,309</u>	<u>\$ 124,207</u>

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

	<b>Three Months Ended March 31,</b>	
	<b>2022</b>	<b>2021</b>
Contract revenue	\$ —	\$ 756
Operating expenses		
Research and development	7,591	3,347
General and administrative	6,189	2,607
Total operating expenses	<u>\$ 13,780</u>	<u>\$ 5,954</u>
Loss from operations	(13,780)	(5,198)
Other income (expense), net		
Interest income	15	47
Interest expense and other, net	—	(188)
Change in estimated fair value of preferred unit warrant	—	(216)
Loss before income taxes	<u>(13,765)</u>	<u>(5,555)</u>
Income tax expense	(63)	(43)
Net loss and comprehensive loss	<u>\$ (13,828)</u>	<u>\$ (5,598)</u>
Net loss attributable to non-controlling interest	(7,605)	(5,598)
Net loss attributable to Rani Therapeutics Holdings, Inc.	<u>\$ (6,223)</u>	<u>\$ —</u>
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted	<u>\$ (0.29)</u>	
Weighted-average Class A common shares outstanding—basic and diluted	<u>21,409</u>	