

**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 10, 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
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 10, 2022, 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, 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**

Exhibit Number	Exhibit Description
99.1	Press Release dated August 10, 2022
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: August 10, 2022

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



Rani Therapeutics Reports Second Quarter 2022 Financial Results; Provides Corporate Update

- Announced positive topline Phase 1 results of RT-102 for the treatment of osteoporosis -

- Anticipate initiating an additional Phase 1 clinical trial in 2H 2022 -

- Capitalized to fund operations into mid-2024 -

SAN JOSE, Calif., August 10, 2022 -- Rani Therapeutics Holdings, Inc. ("Rani Therapeutics", "the Company" or "Rani") (Nasdaq: RANI), a clinical-stage biotherapeutics company focused on the oral delivery of biologics and drugs, today reported financial results for the second quarter ended June 30, 2022 and provided a corporate update.

"Continuing the momentum built in the year since going public, today we announced topline results from the single-ascending portion of our Phase 1 clinical trial with RT-102, the RaniPill™ capsule containing our proprietary formulation of parathyroid hormone (PTH) PTH (1-34), which achieved all of its endpoints," said Talat Imran, Chief Executive Officer of Rani Therapeutics. "Earlier this week, we completed a debt financing which bolsters the Company's financial strength to support advancement of the RaniPill platform and our clinical pipeline. In the coming months, we intend to initiate the Company's third Phase 1 clinical trial, further develop the RaniPill HC, and announce topline data from the repeat-dose portion of the Phase 1 clinical trial of RT-102, which is ongoing. With the expected advancement of two RaniPill programs into the clinic in 2022 and ongoing work on the RaniPill HC, we remain confident in Rani's ability to transform the oral delivery of biologics. I am thankful for our stakeholder's support this past year and look forward to providing updates on our progress through the remainder of 2022."

Second Quarter and Subsequent Highlights

- **Announced Positive Topline Phase 1 Results for RT-102.** In August 2022, Rani announced positive topline results for the single-ascending portion of the Phase 1 clinical study of RT-102, a RaniPill capsule containing PTH for the treatment of osteoporosis. In the study, RT-102 was generally well-tolerated and demonstrating high oral bioavailability, and the RaniPill demonstrated a high drug delivery success rate. The single-center, open label Phase 1 clinical study of RT-102 was initiated in March 2022.
- **Strengthened Financial Position.** In August 2022, the company completed four-year debt financing agreement for up to \$45.0 million with Avenue Capital Group, with \$15.0 million funded at the closing of the loan. Rani intends to use the proceeds to support the continued advancement of the RaniPill platform, ongoing clinical pipeline development, and general operations, and expects the financings to extend its cash runway into mid-2024.

Expected Near-Term Milestones

- Topline results of the repeat-dose portion of the RT-102 clinical study expected in 4Q 2022
- Initiation of an additional Phase 1 clinical trial expected in 2H 2022
- Pre-IND meeting with the FDA for RT-102 in 4Q 2022

Second Quarter Financial Results

- **Cash and cash equivalents** as of June 30, 2022 were \$97.2 million, compared to \$117.5 million for the year ended December 31, 2021.

- **Research and development expenses** for the three months ended June 30, 2022 were \$9.5 million, compared to \$3.8 million for the same period in 2021. The increase was primarily attributed to higher compensation and benefits due to the increase in headcount, including \$1.6 million of non-cash equity-based compensation expense, the ongoing RT-102 Phase 1 clinical trial, and ongoing development of the RaniPill HC.
- **General and administrative expenses** for the three months ended June 30, 2022 were \$6.3 million, compared to \$3.5 million for the same period in 2021. The increase was primarily attributed to public company related costs and higher compensation and benefits due to the increase in headcount, including \$2.1 million of non-cash equity-based compensation expense.
- **Net loss** for the three months ended June 30, 2022 was \$16.0 million, compared to \$5.5 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 and drugs 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.

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 the repeat-dose portion of 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, 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, 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 “may,” “expect,” “could,” “anticipate,” “look forward,” “progress,” “advance,” “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, the impact of the COVID-19 pandemic, 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, 2021 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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RANI THERAPEUTICS HOLDINGS, INC
Condensed Consolidated Balance Sheets
(In thousands, except par value)

	<u>June 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 97,181	\$ 117,453
Prepaid expenses	812	2,142
Total current assets	97,993	119,595
Property and equipment, net	5,352	4,612
Operating lease right-of-use asset	999	—
Total assets	<u>\$ 104,344</u>	<u>\$ 124,207</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,440	\$ 1,080
Related party payable	30	126
Accrued expenses	3,221	1,434
Operating lease liability, current portion	658	—
Total current liabilities	5,349	2,640
Operating lease liability, net current portion	341	—
Total liabilities	5,690	2,640
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value - 20,000 shares authorized; none issued and outstanding as of June 30, 2022 and December 31, 2021	—	—
Class A common stock, \$0.0001 par value - 800,000 shares authorized; 24,494 and 19,712 issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	2	2
Class B common stock, \$0.0001 par value - 40,000 shares authorized; 24,663 and 29,290 issued and outstanding as of June 30, 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 June 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	69,986	55,737
Accumulated deficit	(22,178)	(8,331)
Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc.	47,813	47,411
Non-controlling interest	50,841	74,156
Total stockholders' equity	98,654	121,567
Total liabilities and stockholders' equity	<u>\$ 104,344</u>	<u>\$ 124,207</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Contract revenue	\$ —	\$ 1,961	\$ —	\$ 2,717
Operating expenses				
Research and development	9,528	3,759	17,118	7,106
General and administrative	6,319	3,460	12,509	6,067
Total operating expenses	<u>\$ 15,847</u>	<u>\$ 7,219</u>	<u>\$ 29,627</u>	<u>\$ 13,173</u>
Loss from operations	(15,847)	(5,258)	(29,627)	(10,456)
Other income (expense), net				
Interest income and other, net	35	13	50	60
Interest expense and other, net	—	(169)	—	(357)
Change in estimated fair value of preferred unit warrant	—	(70)	—	(286)
Loss before income taxes	(15,812)	(5,484)	(29,577)	(11,039)
Income tax expense	(154)	(1)	(217)	(44)
Net loss and comprehensive loss	<u>\$ (15,966)</u>	<u>\$ (5,485)</u>	<u>\$ (29,794)</u>	<u>\$ (11,083)</u>
Net loss attributable to non-controlling interest	(8,342)	(5,485)	(15,947)	(11,083)
Net loss attributable to Rani Therapeutics Holdings, Inc.	<u>\$ (7,624)</u>	<u>\$ —</u>	<u>\$ (13,847)</u>	<u>\$ —</u>
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted	<u>\$ (0.31)</u>		<u>\$ (0.60)</u>	
Weighted-average Class A common shares outstanding—basic and diluted	<u>24,371</u>		<u>22,930</u>	

