

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 29, 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 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 29, 2022, 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, 2021. 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	Press Release dated March 29, 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 hereunto duly authorized.

Rani Therapeutics Holdings, Inc.

Date: March 29, 2022

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



Rani Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results; Provides Corporate Update

- *Initiated a Phase 1 clinical trial of RT-102 for the potential treatment of osteoporosis -*
- *Unveiled the high-capacity RaniPill™ HC, capable of delivering payloads of up to 20 mg -*
- *Strengthened Board with the appointments of Lyn Baranowski and Lisa Rometty –*
- *Conference call and webcast today at 4:30 p.m. ET -*

SAN JOSE, Calif., March 29, 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 fourth quarter and full year ended December 31, 2021 and provided a corporate update.

“The year 2021 and the subsequent months that have passed have been a productive period for Rani. We refined and progressed our development pipeline; made strides on RaniPill HC, the high capacity version of our RaniPill platform; bolstered our balance sheet through a successful IPO; and strengthened our board and management with the addition of key personnel,” said Talat Imran, Chief Executive Officer of Rani Therapeutics. “Looking ahead to the rest of 2022, we expect to announce topline results from our Phase 1 trial of RT-102 and initiate an additional Phase 1 trial – the company’s third – in the second half of the year. We also expect to make progress with the RaniPill HC, which adds over 50 potential biologic drug candidates as opportunities for internal development or partnership.”

Fourth Quarter and Subsequent 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.
- **Completed Preclinical GLP 7-Day Repeat Oral Administration Study.** In November 2021, Rani completed a GLP 7-day repeat oral administration study evaluating the safety and tolerability of RT-102 in canines. In the study, no safety events were observed.
- **Additions to the Board of Directors.** In January 2022 and November 2021, Rani strengthened its Board of Directors with the appointments of Lisa Rometty and Lyn Baranowski, respectively. Ms. Rometty has more than two decades of global commercialization and product development experience in the biotechnology and healthcare space. Ms. Baranowski is a seasoned biotechnology executive with a diverse set of knowledge around product portfolios and therapeutic areas.

Expected Near-Term Milestones

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

Full Year 2021 Financial Results

- **Cash and cash equivalents** as of December 31, 2021 were \$117.5 million, compared to \$73.1 million as of December 31, 2020. 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 (R&D) expenses** for the three and twelve months ended December 31, 2021 were \$7.4 million and \$26.5 million, respectively, compared to \$3.3 million and \$12.0 million for the same periods in 2020, respectively. The increases were primarily attributed to higher compensation and benefits due to the increase in headcount, including \$8.2 million for the full-year of non-cash equity-based compensation expense; of which \$6.2 million was recognized in connection with the company's IPO and related corporate reorganization in the third quarter of 2021.

- **General and administrative expenses** for the three and twelve months ended December 31, 2021 were \$5.9 million and \$27.8 million, respectively, compared to \$1.8 million and \$5.0 million for the same periods in 2020, respectively. The increases were primarily attributed to the public company related costs and higher compensation and benefits due to the increase in headcount, including \$14.4 million for the full-year of non-cash equity-based compensation expense; of which \$10.7 million was recognized in connection with the company's IPO and related corporate reorganization in the third quarter of 2021.
- **Net loss** for the three and twelve months ended December 31, 2021 was \$13.3 million and \$53.1 million, respectively, compared to \$5.8 million and \$16.7 million for the same periods in 2020, respectively.

Conference Call

Rani will host a corresponding conference call and live webcast at 1:30 p.m. PT / 4:30 p.m. ET on March 29, 2022 to discuss the results and provide a business update. Individuals interested in listening to the live conference call may do so by dialing (844) 605-7369 for domestic callers, or (929) 517-0917 for international callers and reference conference ID: 7192045; or from the webcast link in the investor relations section of the company's website at: 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.

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 the RaniPill™ capsule, which is a novel, proprietary and patented platform technology, intended to replace subcutaneous injection of biologics with oral dosing. Rani has successfully conducted several preclinical and clinical studies to evaluate safety, tolerability and bioavailability using the RaniPill™ capsule. For more information, visit www.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, 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 materially from those expressed or implied by such forward-looking statements. Words such as “may,” “could,” “prospective,” “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.

Investor Contact:

investors@ranitherapeutics.com

Media Contact:

media@ranitherapeutics.com

Source: Rani Therapeutics

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Rani Therapeutics Holdings, Inc.
Consolidated Balance Sheets
(In Thousands, Except Par Value)

	<u>Year End December 31,</u>	
	<u>2021</u>	<u>2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 117,453	\$ 73,058
Related party note receivable	—	1,720
Prepaid expenses	2,142	167
Total current assets	119,595	74,945
Property and equipment, net	4,612	4,470
Total assets	<u>\$ 124,207</u>	<u>\$ 79,415</u>
Liabilities, Convertible Preferred Units and Stockholders' Equity / Members' Deficit		
Current liabilities:		
Accounts payable	\$ 1,080	\$ 537
Related party payable	126	145
Accrued expenses	1,434	550
Deferred revenue	—	2,717
Current portion of long-term debt	—	1,359
Total current liabilities	2,640	5,308
Preferred unit warrant liability	—	320
Long-term debt, less current portion	—	2,412
Total liabilities	2,640	8,040
Commitments and contingencies		
Convertible preferred units	—	184,714
Stockholders' equity / (members' deficit):		
Common units	—	664
Preferred stock, \$0.0001 par value - 20,000 shares authorized; none issued and outstanding as of December 31, 2021	—	—
Class A common stock, \$0.0001 par value - 800,000 shares authorized; 19,712 issued and outstanding as of December 31, 2021	2	—
Class B common stock, \$0.0001 par value - 40,000 shares authorized; 29,290 issued and outstanding as of December 31, 2021	3	—
Class C common stock, \$0.0001 par value - 20,000 shares authorized; none issued and outstanding as of December 31, 2021	—	—
Additional paid-in capital	55,737	—
Accumulated deficit	(8,331)	(114,003)
Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc. / (members' deficit)	47,411	(113,339)
Non-controlling interest	74,156	—
Total stockholders' equity / (members' deficit)	121,567	(113,339)
Total liabilities, convertible preferred units and stockholders' equity / (members' deficit)	<u>\$ 124,207</u>	<u>\$ 79,415</u>

Rani Therapeutics Holdings, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In Thousands, Except Per Share Amounts)

	<u>Three Months Ended December 31,</u>		<u>Year Ended December 31,</u>	
	2021	2020	2021	2020
Contract revenue	\$ —	\$ 210	\$ 2,717	\$ 462
Operating expenses				
Research and development	7,417	3,336	26,482	12,044
General and administrative	5,945	1,818	27,834	4,962
Total operating expenses	<u>\$ 13,362</u>	<u>\$ 5,154</u>	<u>\$ 54,316</u>	<u>\$ 17,006</u>
Loss from operations	(13,362)	(4,944)	(51,599)	(16,544)
Other income (expense), net				
Interest income	16	(24)	89	63
Loss on extinguishment of debt	—	—	(700)	—
Interest expense and other, net	1	(58)	(466)	(124)
Change in estimated fair value of preferred unit warrant	—	(718)	(371)	(63)
Loss before income taxes	(13,345)	(5,744)	(53,047)	(16,668)
Income tax expense	40	(12)	(41)	(35)
Net loss and comprehensive loss	<u>\$ (13,305)</u>	<u>\$ (5,756)</u>	<u>\$ (53,088)</u>	<u>\$ (16,703)</u>
Net loss attributable to non-controlling interest	(8,116)	(5,756)	(44,757)	(16,703)
Net loss attributable to Rani Therapeutics Holdings, Inc.	<u>\$ (5,189)</u>	<u>\$ —</u>	<u>\$ (8,331)</u>	<u>\$ —</u>
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted	<u>\$ (0.27)</u>		<u>\$ (0.43)</u>	
Weighted-average Class A common shares outstanding—basic and diluted	<u>19,439</u>		<u>19,534</u>	