

**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): November 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:**

| <b>Title of each class</b>                         | <b>Trading<br/>Symbol(s)</b> | <b>Name of each exchange on which registered</b> |
|--|------------------------------|--|
| 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 November 10, 2022, Rani Therapeutics Holdings, Inc. (the “Company”) issued a press release providing a corporate update and announcing its financial results for the third quarter ended September 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**

| <b>Exhibit<br/>Number</b> | <b>Exhibit Description</b>  |
|---------------------------|---|
| 99.1                      | <a href="#">Press Release dated November 10, 2022</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: November 10, 2022

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

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## Rani Therapeutics Reports Third Quarter 2022 Financial Results and Provides Corporate Update

- RT-102 Phase 1 topline repeat-dose data anticipated in 4Q 2022 -

- Announced preclinical development of RT-111, a RaniPill GO capsule containing ustekinumab biosimilar for the potential treatment of psoriatic arthritis, ulcerative colitis, Crohn's disease and psoriasis -

- Announced RT-102 Phase I single-dose topline results -

**SAN JOSE, Calif., November 10, 2022** -- 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 September 30, 2022, and provided a corporate update.

"I am delighted with what Rani has been able to accomplish so far this year, highlighted by the recent announcements of the latest RaniPill program RT-111, and positive topline data from Part 1 of the Phase 1 study of RT-102," said Talat Imran, Chief Executive Officer of Rani Therapeutics. "In the remainder of the year, we expect to announce topline data from Part 2 of the Phase 1 study of RT-102, which will provide the first repeat-dose data of the RaniPill capsule in humans. Additionally, we intend to continue to build out the RaniPill platform by beginning in vivo studies of a fully-autonomous RaniPill HC by year-end. Turning to 2023, we expect to initiate a Phase 2 study of RT-102 and to progress three additional assets into Phase 1 studies during the year as we advance the clinical development of our pipeline."

### Third Quarter 2022 and Subsequent Highlights

- **Announced the preclinical development of RT-111.** In October 2022, the company announced that it had begun preclinical development of RT-111, a RaniPill GO containing a biosimilar of STELARA® (ustekinumab) for the potential treatment of psoriatic arthritis, ulcerative colitis, Crohn's disease and psoriasis. Rani intends to initiate a Phase 1 study for RT-111 in 2023.
- **Announced Positive Topline Phase 1 Results for RT-102.** In August 2022, Rani announced positive topline results from Part 1 of the Phase 1 clinical study of RT-102, the RaniPill GO containing a proprietary formulation of human parathyroid hormone (PTH) for the potential treatment of osteoporosis. RT-102 was generally well-tolerated and orally delivered 20µg and 80µg of PTH with 300-400% greater bioavailability of PTH than subcutaneous Forteo® (teriparatide) 20µg. Rani anticipates announcing topline data from Part 2 of the Phase 1 study in the fourth quarter of 2022.
- **Entered into a Loan Agreement with Avenue Venture Opportunities.** In August 2022, Rani entered into a loan and security agreement and related supplement with Avenue Venture Opportunities Fund, L.P. The loan agreement provides for term loans in an aggregate principal amount up to \$45.0 million. A loan of \$30.0 million was committed at closing, with \$15.0 million funded immediately and \$15.0 million available to be drawn between October 1, 2022 and December 31, 2022. The remaining \$15.0 million of loans is uncommitted and is subject to certain conditions and approval by the lender.
- **Entered into a Sales Agreement for "At-the-Market Offerings."** In August 2022, Rani entered into a Controlled Equity<sup>SM</sup> Sales Agreement with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC, collectively the Agents, pursuant to which Rani may offer and sell from time to time through the Agents up to \$150 million of shares of its Class A common stock, in such share amounts as Rani may specify by notice to the Agents, in accordance with the terms and conditions set forth in the sales agreement.

### Expected Near-Term Milestones

- RT-102 – Phase 1 Part 2 topline repeat-dose data expected in the fourth quarter of 2022
- RT-102 – Investigational New Drug (IND) application, followed by Phase 2 initiation in the second half of 2023
- Initiation of three additional Phase 1 studies in 2023 with pipeline molecules:
  - o RT-105 containing an adalimumab biosimilar
  - o RT-110 containing PTH for hypo-parathyroidism
  - o RT-111 containing an ustekinumab biosimilar for psoriatic arthritis, ulcerative colitis, Crohn’s disease and psoriasis

### Third Quarter Financial Results

- **Cash, cash equivalents, restricted cash equivalents and marketable securities** as of September 30, 2022 totaled \$98.7 million, compared to cash and cash equivalents of \$117.5 million for the year ended December 31, 2021. There were no restricted cash equivalents or marketable securities in the prior comparative period.
- **Research and development expenses** for the three months ended September 30, 2022 were \$9.1 million, compared to \$12.0 million for the same period in 2021. The difference was primarily attributed to a decrease of \$4.9 million in equity-based compensation due to Rani's non-recurring initial public offering (IPO) and related organizational transactions in the three months ended September 30, 2021, partially offset by an increase of \$1.7 million in salaries and related benefit costs due to higher headcount, and an increase in facilities, materials and supplies expenses of \$0.5 million.
- **General and administrative expenses** for the three months ended September 30, 2022 were \$7.2 million, compared to \$15.8 million for the same period in 2021. The difference was primarily attributed to a decrease of \$9.4 million in equity-based compensation due to Rani's non-recurring IPO and related organizational transactions in the three months ended September 30, 2021, partially offset by an increase of \$0.4 million in salaries and related benefit costs due to higher headcount, and an increase of \$0.4 million in third-party services and other costs.
- **Net loss** for the three months ended September 30, 2022 was \$16.2 million, compared to \$28.7 million for the same period in 2021, including \$4.6 million and \$19.6 million of non-cash charges, primarily equity-based compensation expense, for the three months ended September 30, 2022 and 2021, respectively.

### 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 timing of topline results from the repeat-dose portion of Rani’s Phase 1 trial of RT-102, the expected initiation of in vivo studies with a fully-autonomous RaniPill HC, the expected filing of an IND and initiation of a Phase 2 trial of RT-102 in 2023, the expected initiation of three Phase 1 trials of other product candidates in 2023, 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, availability of additional tranches under its loan agreement, the potential to undertake “at-the-market offerings” of equity securities under its sales agreement with Agents, 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.

## **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**  
**Condensed Consolidated Balance Sheets**  
(In thousands, except par value)

|   | September 30,<br>2022<br>(Unaudited) | December 31,<br>2021 |
|---|--------------------------------------|----------------------|
| <b>Assets</b>   |                                      |                      |
| Current assets:   |                                      |                      |
| Cash and cash equivalents   | \$ 27,219                            | \$ 117,453           |
| Marketable securities   | 70,952                               | —                    |
| Prepaid expenses and other current assets   | 2,549                                | 2,142                |
| Total current assets  | 100,720                              | 119,595              |
| Restricted cash equivalents   | 500                                  | —                    |
| Property and equipment, net   | 5,680                                | 4,612                |
| Operating lease right-of-use asset  | 1,302                                | —                    |
| Total assets  | \$ 108,202                           | \$ 124,207           |
| <b>Liabilities and Stockholders' Equity</b>   |                                      |                      |
| Current liabilities:  |                                      |                      |
| Accounts payable  | \$ 1,790                             | \$ 1,080             |
| Related party payable   | 55                                   | 126                  |
| Accrued expenses  | 4,357                                | 1,434                |
| Operating lease liability, current portion  | 984                                  | —                    |
| Total current liabilities   | 7,186                                | 2,640                |
| Operating lease liability, less current portion   | 318                                  | —                    |
| Long-term debt  | 14,091                               | —                    |
| Total liabilities   | 21,595                               | 2,640                |
| Commitments and contingencies   |                                      |                      |
| Stockholders' equity:   |                                      |                      |
| Preferred stock, \$0.0001 par value - 20,000 shares authorized; none issued and outstanding as of September 30, 2022 and December 31, 2021                                  | —                                    | —                    |
| Class A common stock, \$0.0001 par value - 800,000 shares authorized; 24,720 and 19,712 issued and outstanding as of September 30, 2022 and December 31, 2021, respectively | 2                                    | 2                    |
| Class B common stock, \$0.0001 par value - 40,000 shares authorized; 24,639 and 29,290 issued and outstanding as of September 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 September 30, 2022 and December 31, 2021                             | —                                    | —                    |
| Additional paid-in capital  | 72,379                               | 55,737               |
| Accumulated other comprehensive loss  | (57)                                 | —                    |
| Accumulated deficit   | (30,133)                             | (8,331)              |
| Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc.   | 42,194                               | 47,411               |
| Non-controlling interest  | 44,413                               | 74,156               |
| Total stockholders' equity  | 86,607                               | 121,567              |
| Total liabilities and stockholders' equity  | \$ 108,202                           | \$ 124,207           |

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

|   | For the Three Months Ended September<br>30, |                    | For the Nine Months Ended September<br>30, |                    |
|---|---|--------------------|--|--------------------|
|   | 2022  | 2021               | 2022                                       | 2021               |
| Contract revenue  | \$ —  | \$ —               | \$ —                                       | \$ 2,717           |
| Operating expenses  |   |                    |  |                    |
| Research and development  | 9,103                                       | 11,959             | 26,221                                     | 19,065             |
| General and administrative  | 7,239                                       | 15,822             | 19,748                                     | 21,889             |
| Total operating expenses  | <u>\$ 16,342</u>                            | <u>\$ 27,781</u>   | <u>\$ 45,969</u>                           | <u>\$ 40,954</u>   |
| Loss from operations  | (16,342)                                    | (27,781)           | (45,969)                                   | (38,237)           |
| Other income (expense), net   |   |                    |  |                    |
| Interest income and other, net  | 379   | 13                 | 430  | 73                 |
| Loss on extinguishment of debt  | —   | (700)              | —  | (700)              |
| Interest expense and other, net   | (352)                                       | (110)              | (352)                                      | (467)              |
| Change in estimated fair value of preferred unit warrant  | —   | (85)               | —  | (371)              |
| Loss before income taxes  | (16,315)                                    | (28,663)           | (45,891)                                   | (39,702)           |
| Income tax expense  | 107   | (37)               | (111)                                      | (81)               |
| Net loss  | <u>\$ (16,208)</u>                          | <u>\$ (28,700)</u> | <u>\$ (46,002)</u>                         | <u>\$ (39,783)</u> |
| Net loss attributable to non-controlling interest   | (8,253)                                     | (25,558)           | (24,200)                                   | (36,641)           |
| Net loss attributable to Rani Therapeutics Holdings, Inc.   | <u>\$ (7,955)</u>                           | <u>\$ (3,142)</u>  | <u>\$ (21,802)</u>                         | <u>\$ (3,142)</u>  |
| Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted | <u>\$ (0.33)</u>                            | <u>\$ (0.16)</u>   | <u>\$ (0.93)</u>                           | <u>\$ (0.16)</u>   |
| Weighted-average Class A common shares outstanding—basic and diluted                                  | <u>24,468</u>                               | <u>19,437</u>      | <u>23,449</u>                              | <u>19,437</u>      |



