**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):**

**December 06, 2022**



**Rani Therapeutics Holdings, Inc.**

**(Exact name of Registrant as Specified in Its Charter)**



|  |  |  |
| --- | --- | --- |
| **Delaware** | **001-40672** | **86-3114789** |
| **(State or Other Jurisdiction** | **(Commission File Number)** | **(IRS Employer** |
| **of Incorporation)** |  | **Identification No.)** |
| **2051 Ringwood Avenue** |  |  |
| **San Jose, California** |  | **95131** |
| **(Address of Principal Executive Offices)** |  | **(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:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Trading** |  |  |
| **Title of each class** |  | **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 7.01 Regulation FD Disclosure.**

On December 6, 2022, Rani Therapeutics Holdings, Inc. (the “Company” or “Rani”) issued a press release to announce topline results from Part 2 of the RT-102 Phase 1 study. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The Company is also furnishing a copy of a presentation (the “Presentation”) that the Company intends to use, in whole or in part, during discussions with.external parties A copy of the Presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

All of the information furnished in this Item 7.01 and Item 9.01 (including Exhibit 99.1 and Exhibit 99.2) shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (“Exchange Act”), and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 8.01 Other Events.**

On December 6, 2022, Rani announced topline results from Part 2 of the RT-102 Phase 1 study.

**Study Design**

Part 2 is a continuation of Rani’s single-center, open-label Phase 1 study of RT-102, a RaniPill™ GO capsule containing parathyroid hormone (1-34) analog (PTH), conducted in Australia. The study evaluated the safety and tolerability of once-daily administration of RT-102 containing 20μg of PTH given repeatedly for seven consecutive days in 10 healthy female volunteers (5 of whom were post-menopausal). Complete pharmacokinetic profiles of PTH were obtained for each subject on Day 7.

**Topline Results**

*Safety and Tolerability*

* RT-102 was generally well tolerated, with no serious adverse events (SAEs) noted during the study

oNone of the participants withdrew from the repeat-dose study due to any adverse event related to the RaniPill™ capsule or due to difficulty swallowing the capsule

oTwo subjects had transient, mild-to-moderate adverse events which resolved without any intervention

* Device remnants were excreted without sequelae in all subjects

*Device Performance*

* In all 10 participants who completed seven days of daily, consecutive dosing, the RaniPill™ GO capsule demonstrated an overall drug delivery success rate of 91% over the seven days (drug sampling was done at three, six and nine hours after capsule swallowing on Days 1-6)
* On Day 7, with more frequent, serial drug sampling after capsule swallowing on that day, the drug delivery success rate was 100%
* On Days 1 through 6, participants ate food three hours after administration of the RaniPill™ GO capsule. The number of successful deployments was comparable before and after food was consumed

*Pharmacokinetics*

* RT-102 delivered 20µg of PTH with high bioavailability (relative to 20µg subcutaneous Forteo® (teriparatide) in Part 1 of the study), confirming the high bioavailability of PTH delivered via the RaniPill™ capsule observed during Part 1 of the Phase 1 study

This report contains "forward-looking" statements, including statements regarding topline results from Part 2 of the RT-102 Phase 1 study. Actual results may differ materially from those set forth in this report due to the risks and uncertainties inherent in research and development, including the risk that initial (or topline) clinical results do not report on all data from a clinical trial that may be important for development or regulatory approval, the risk that results from earlier clinical trials may not be indicative of future clinical results, as well as other risks detailed in the "Risk Factors" section of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2021 as well as discussions of potential risks, uncertainties and other important factors in the Company’s other filings with the U.S. Securities and Exchange Commission. The Company undertakes no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.



**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Exhibit** |  |  |  |  |  |  |
| **Number** |  |  | **Exhibit Description** | | | |
| 99.1 |  |  | Press Release of Rani Therapeutics Holdings, Inc. dated December 6, 2022 | | |  |
| 99.2 |  |  | Presentation dated December 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: December 6, 2022 By: /s/ Svai Sanford



Svai Sanford

Chief Financial Officer



**Exhibit 99.1**



**Rani Therapeutics Announces Repeat-Dose Topline Results from RT-102 Phase 1 Study** *- RT-102 achieved all of its endpoints in the repeat-dose Part 2 of the Phase 1 Study - - Repeat doses of RT-102 were generally well tolerated, with no serious adverse events - - RaniPill™ GO delivered PTH to subjects with a 91% success rate and demonstrated high bioavailability - - Data from Part 1 and Part 2 of the Phase 1 study of RT-102 support advancement to a Phase 2 study –*

**SAN JOSE, Calif., December 6, 2022** -- Rani Therapeutics Holdings, Inc. (“Rani Therapeutics” or “Rani”) (Nasdaq: RANI), a clinical-stage biotherapeutics company focusedon the oral delivery of biologics and drugs, today announced topline results from Part 2 (repeat-dose portion) of the Phase 1 study of RT-102, the RaniPill™ GO capsule containing a proprietary formulation of human parathyroid hormone (1-34) analog (PTH) being developed for the treatment of osteoporosis. The study achieved all of its endpoints, with repeat doses of RT-102 being generally well tolerated and delivering drug with high reliability to participants via the RaniPill™ GO.

“The data are highly encouraging and reinforce the tolerability and high bioavailability of RT-102 that was observed in Part 1 of the study,” said Mir Hashim, PhD, Chief Scientific Officer of Rani. “The RaniPill™ GO capsule continues to deliver drug payloads to subjects at success rates exceeding 90%. Importantly, we believe the safety, reliability, and pharmacokinetic data that we collected through both parts of the Phase 1 study support the initiation of a Phase 2 trial of RT-102 in osteoporosis, which we anticipate beginning in the second half of 2023.”

With these data, in total, 185 RaniPill™ GO capsules have now been administered to more than 90 participants in clinical studies, in addition to over 1,700 RaniPill™ capsules administered to animals in preclinical studies. In the clinical studies, the RaniPill™ capsule has been well tolerated and delivered its drug payload with high reliability and with bioavailability comparable to or better than subcutaneous injection.

“The repeat-dose data contribute to our growing body of preclinical and clinical data that we believe support the viability of the RaniPill™ platform to orally deliver biologics and drugs to treat chronic diseases,” said Talat Imran, Chief Executive Officer of Rani. “These data give us confidence to move forward with multiple programs in parallel, including our ustekinumab biosimilar and adalimumab biosimilar programs, and to expand manufacturing scale-up. We can see a future where millions of patients no longer carry the burden of regular injections.”

**Study Design**

Part 2 is a continuation of Rani’s single-center, open-label Phase 1 study of RT-102 conducted in Australia. The study evaluated the safety and tolerability of once-daily administration of RT-102 containing 20μg of PTH given repeatedly for seven consecutive days in 10 healthy female volunteers (5 of whom were post-menopausal). Complete pharmacokinetic profiles of PTH were obtained for each subject on Day 7.

**Topline Results**

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* On Days 1 through 6, participants ate food three hours after administration of the RaniPill™ GO capsule. The number of successful deployments was comparable before and after food was consumed

*Pharmacokinetics*

* RT-102 delivered 20µg of PTH with high bioavailability (relative to 20µg subcutaneous Forteo® (teriparatide) in Part 1 of the study), confirming the high bioavailability of PTH delivered via the RaniPill™ capsule observed during Part 1 of the Phase 1 study
* These data indicate that PTH delivered via RT-102 (RaniPill™ GO capsule) may be efficacious at doses lower than 20μg

**Conference Call and Webcast**

Rani will host a conference call and live webcast at 4:30 pm ET / 1:30 pm PT on December 6, 2022, to discuss the topline results from the Phase 1 Part 2 repeat dose study of RT-

1. Individuals interested in listening to the conference will need to register for the event here or through the link provided in the investor relations section on the company’s website. The webcast will be available for replay for approximately 180 days.

**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™ 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 expected filing of an investigational new drug application and initiation of a Phase 2 trial of RT-102 in 2023, the expected initiation of additional Phase 1 trials of other product candidates in 2023, the prospects for RT-102 being efficacious at doses lower than 20µg, the ability of the data from the Phase 1 study of RT-102 to support progressing to a Phase 2 trial of RT-102, the viability of the RaniPill™ platform to orally deliver biologics and drugs to treat chronic diseases, Rani’s advancement of its preclinical and clinical programs and timing of results, Rani’s development and advancement of its RaniPill™ capsule technology, the impact of its technology on medical treatment, the potential benefits of the RaniPill™ capsule technology, patient and physician acceptance of the RaniPill™ technology, and the ability of Rani to expand manufacturing scale-up. 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,” “anticipate,” “believe,” “look forward,” “progress,” “advance,” “potential”, “be able to” 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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