

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 14, 2023

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 8.01 Other Events.

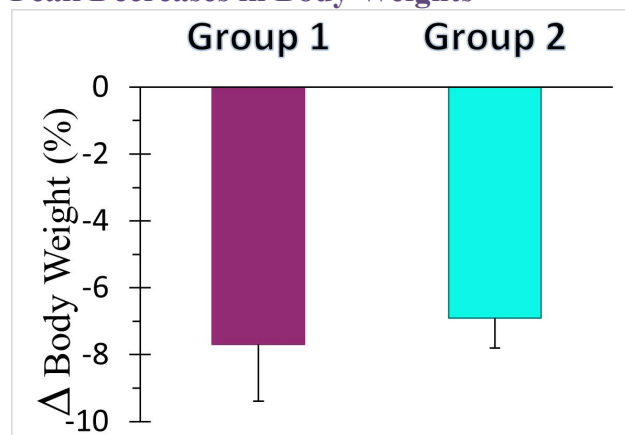
On December 14, 2023, Rani Therapeutics Holdings, Inc. issued a press release to announce preclinical data regarding a unimolecular triagonist molecule delivered via endoscope and an update regarding timing of the initiation of its RT-102 Phase 2 clinical study.

Data Highlights

The recent preclinical study evaluated the pharmacokinetic (PK) and pharmacodynamic (PD) profiles of an incretin triagonist (GLP-1, GIP, glucagon receptors) when delivered via endoscope-guided transenteric administration to mimic the RaniPill route of administration, versus the traditional administration route of subcutaneous (SC) injection. The study was conducted in canines separated into two groups. In Group 1 (N=5), 0.12 mg/kg of drug was administered via transenteric delivery by endoscope. In Group 2 (N=5), 0.12 mg/kg of drug was administered by subcutaneous injection. Blood samples were collected over 2 weeks for analysis of serum drug concentrations and various PD and safety biomarkers.

A single dose of drug delivered via either transenteric or SC routes elicited rapid decreases in body weight and serum lipids. Weight loss is believed to be due to early satiety leading to reduced caloric intake. The drug was well tolerated in both groups with no serious adverse events (SAEs) observed or changes in safety markers examined.

Peak Decreases in Body Weights



Group 1: Endoscopic (N=5)

Group 2: SC (N=5)

All data are Means \pm SE

Near-Term Milestone Expectations

- Initiation of Phase 2 clinical trial of RT-102, a RaniPill GO containing teriparatide for osteoporosis, expected in 2024.
- Topline results of Phase 1 clinical trial of RT-111, a RaniPill GO containing ustekinumab biosimilar CT-P43, expected in the first quarter of 2024.
- Development of RaniPill HC to be ready for potential Phase 1 clinical trials in the second half of 2024.

Forward-Looking Statements

Statements contained in this Current Report on Form 8-K 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 initiation of a Phase 2 clinical trial of RT-102 in 2024, the potential opportunity for the RaniPill platform to support oral delivery of multiple obesity drug products, the expected timing of topline results from the RT-111 Phase 1 clinical trial in the first quarter of 2024, the expected readiness of the RaniPill HC for clinical development in the second half of 2024, the potential for the transenteric delivery via endoscope of an incretin triagonist to mimic the RaniPill route of delivery, the likelihood that weight loss in the preclinical study of the incretin triagonist was caused by early satiety leading to reduced caloric intake, the belief that the preclinical data are reflective of the potential contributions the RaniPill capsule can make to the GLP-1 receptor agonist space and the broader obesity market, and the potential for Rani to use the RaniPill platform to create oral alternatives for single and multiagonist drugs with differentiated dosing flexibility. 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

“potential,” “expected,” “believed,” 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 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, 2022, and subsequent filings and reports by Rani. All forward-looking statements contained in this Form 8-K 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.

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 14, 2023

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