

**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
(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 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
 - o None 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
 - o Two 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



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 focused on 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

Safety and Tolerability

- RT-102 was generally well tolerated, with no serious adverse events (SAEs) noted during the study
 - o None 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
 - o Two 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
- 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-102. 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.

Investor Contact:

investors@ranitherapeutics.com

Media Contact:

media@ranitherapeutics.com

RT-102 Phase I Study Part 2: Repeat-Dose Update



December 2022

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Forward-Looking Statements

This presentation and the accompanying oral statements contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 as contained in Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act. Forward-looking statements are based on information available at the time those statements are made or on management's good faith beliefs and assumptions as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in, or suggested by, the forward-looking statements. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this presentation and the accompanying oral statements may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements. These risks and uncertainties include Rani Therapeutics Holdings, Inc.'s ("Rani," "we," "us," or "our") future financial performance, including our expectations regarding our revenues, cost of revenues, operating expenses, and our ability to achieve and maintain future profitability, those risks inherent in the preclinical and clinical development process and the regulatory approval process, the risks and uncertainties in commercialization and gaining market acceptance, the commercial potential of oral biologics, our ability to complete development of the RaniPill® HC or any redesign and conduct additional preclinical and clinical studies of the RaniPill HC or any future design of the RaniPill to accommodate higher target payloads, the risks associated with protecting and defending our patents or other proprietary rights, the risk that our proprietary rights may be insufficient to protect our product candidates, the risk that we will be unable to obtain necessary capital when needed on acceptable terms or at all, our ability to enter into strategic partnerships and to achieve the potential benefits of such partnerships, competition from other products or procedures, our reliance on third-parties to conduct our clinical and non-clinical trials, our reliance on single-source third-party suppliers to manufacture clinical, non-clinical and any future commercial supplies of our product candidates, our ability to continue to scale and optimize our manufacturing processes by expanding our use of automation, our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act, the extent and duration of the COVID-19 pandemic and the conflict between Ukraine and Russia, our expectations regarding customer demand for our product candidates, increased regulatory requirements and other factors that are set forth in our filings with the Securities and Exchange Commission ("SEC"), including under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, which was filed with the SEC on May 11, 2022, and our other public filings made with the SEC and available at www.sec.gov.

Trade names, trademarks and service marks of other companies appearing in this presentation are the property of their respective owners. Solely for convenience, the trademarks and trade names referred to in this presentation 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.

Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will" or "would," or the negative of these terms or other comparable terminology. You should not put undue reliance on any forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved, if at all. Except as required by law, Rani does not undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

This presentation and the accompanying oral statements contain statistical data, estimates and forecasts that are based on independent industry publications or other publicly available information, as well as other information based on our internal sources. This information involves many assumptions and limitations, and you are cautioned not to give undue weight to such information. We have not independently verified the accuracy or completeness of the information contained in the industry publications and other publicly available information. Accordingly, we make no representations as to the accuracy or completeness of that information nor do we undertake to update such information after the date of this presentation.

Presentation Overview

- Topline results from Part 2 of our RT-102 Phase 1 study
 - Seven-day repeat-dose study in healthy volunteers
- First repeat-dose study of RaniPill capsule in humans collecting data on:
 - Safety
 - Tolerability
 - Device Reliability
- Important data
 - For the RT-102 program and Phase 2 plan for 2023
 - For RaniPill platform in general

RT-102 Phase 1 Study Design

Objective: To Evaluate the Safety, Tolerability and Pharmacokinetics of Parathyroid Hormone (1-34) (PTH) Administered Orally via RaniPill™ Capsule

Part 1 : Single ascending doses of RT-102

- RT-102 Group 1: 20µg (N=15)
- RT-102 Group 2: 80µg (N=15)
- Control Group: Forteo® SC 20µg (N=10)

Part 2: Repeat-doses of RT-102

- Once daily dose of RT-102 20µg for 7 days in healthy and post-menopausal women (N=10)

Part 1 Summary

- Safety & Tolerability
 - Both doses of RT-102 were well tolerated
 - No serious adverse events (SAEs) reported in the study
 - No adverse events (AEs) related to RaniPill reported
- Device Performance
 - Drug delivery success rate of 95%
- Pharmacokinetics
 - Bioavailability of PTH delivered via RT-102 was >300% higher than subcutaneous (SC) injection

Part 2:
Arvinder Dhalla, PhD
Vice President, Clinical Development



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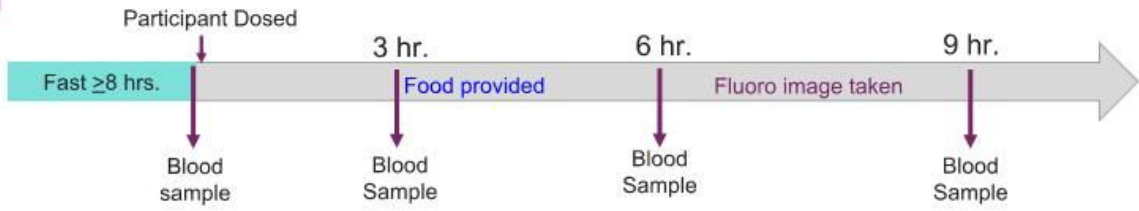
Part 2 Study Overview

A Phase I Study to Evaluate the Pharmacokinetics of Parathyroid Hormone (1-34) (PTH) Administered Orally via RaniPill™ Capsule

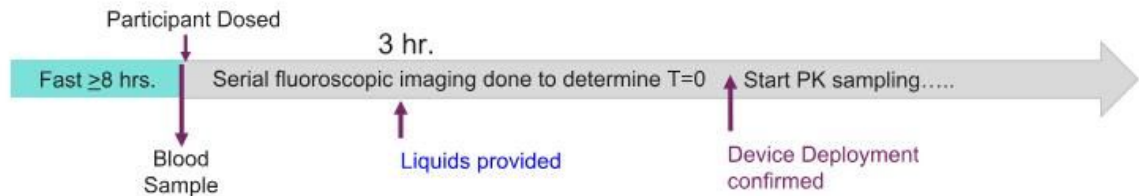
Objective	To evaluate the safety and tolerability of repeat-doses of RT-102
Study Population	Healthy women and Post-menopausal women (N=10)
Study Site	Single Site in Australia
Study Group	A single group receiving RT-102 20µg dose for 7 days
End Points	<ul style="list-style-type: none">• Safety and tolerability of repeat-doses of RT-102• Reliability of drug delivery
Start Date	August 1, 2022

Repeat-Dose: Study Procedures

Days 1-6



Day 7



Participation in the study was considered complete if a participant was able to complete all doses for 7 days and go through pharmacokinetic sampling on Day 7



Topline Results

Study Demographics

	Healthy Women	Post-Menopausal
	N=5	N=5
Age	25.6 years (22 - 35)	60 years (54 - 65)
Race	% (n/N)	% (n/N)
Hispanic	20 (1/5)	0 (0/5)
White-non-hispanic	20 (1/5)	100 (5/5)
Asian	40 (2/5)	0 (0/5)
Asian-Pacific Islander	20 (1/5)	0 (0/5)
	Mean ± SD (Min - Max)	Mean ± SD (Min - Max)
Weight (kg)	60.6 ± 9.8 (50.2 - 76)	64.3 ± 10.1 (55.6 - 75.4)
Body Mass Index (kg/m²)	23.7 ± 2.5 (20.4 - 26.9)	25.3 ± 5 (20.9 - 31.7)

Exclusions after Enrollment

- Enrollment was done on a rolling basis to complete ten subjects, total number of participants enrolled were 17
- Seven participants did not complete 7 days of dosing due to exclusions per protocol
 - Two participants started menstruation on Day 4
 - One participant had cannulation issues on Day 7
 - One participant had elevated eosinophils on Day 4 due to an earring infection
 - One participant had >7 hr. gastric residence time (GRT) on Day 7
 - Two participants had pill remnants exceeding the number (≥ 3) allowed by protocol

None of the participants stopped the dosing due to any adverse events related to the RaniPill

Adverse Events

	Adverse Event	Incidence
PTH-related	Constipation*	1 (10%)
	Diarrhea*	1 (10%)
RaniPill-related	Abdominal Pain	1 (10%)

Daily Drug Delivery by RaniPill with Repeat-Dosing

Drug signal detected in 63 out of 69 deployments* = **at least 91% Success Rate**

#	Subject Type	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
1	HW	✓	✓	✓	✓	✓	✓	✓
2	HW	✓	✓	✓	✓	✓	✓	✓
3	HW	✓	✗	✓	✓	✓	✓	✓
4	HW	✗	✓	✓	✓	✓	✓	✓
5	HW	✓	✗	✓	✓	✓	✓	✓
6	PM	✓	✓	✓	✓	✓	✓	✓
7	PM	✗	✓	✓	✓	✓	✓	✓
8	PM	NA	✓	✓	✗	✓	✗	✓
9	PM	✓	✓	✓	✓	✓	✓	✓
10	PM	✓	✓	✓	✓	✓	✓	✓

*Deployment confirmed by imaging but not tracked; samples taken at 3 hr. intervals post-dose. Some misses could be due to mismatch of sampling and deployment time

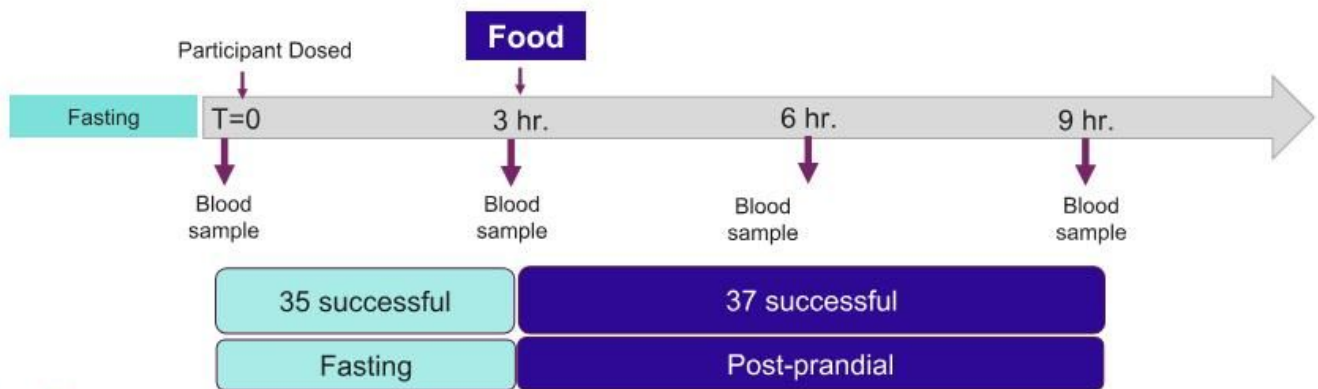


HW: healthy women, PM: post-menopausal,
✓ indicates drug signal detected, ✗ indicates drug signal not detected
NA: Pill not deployed at the time of blood sampling

Presence of Food Did Not Impact Device Performance

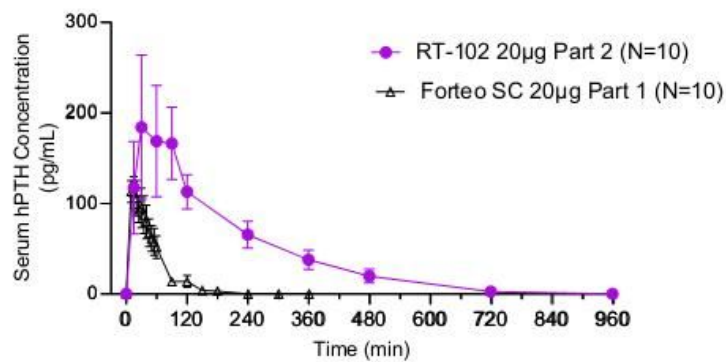
- On Days 1-6, food was consumed at 3 hrs. after capsule administration to all enrolled subjects
- During this period, there were a total of 72 successful deployments
- 35 were recorded before food was consumed (fasted)
- 37 were recorded after food was consumed (post-prandial)

These data suggest that drug delivery by the RaniPill was unaffected by presence of food



PK Profile of PTH Delivered via RaniPill

Drug levels were observed in all 10 subjects on Day 7 = 100% success rate



- These data corroborate the high bioavailability observed in Part 1 and suggest that RT-102 may be efficacious at doses lower than 20µg

Repeat Doses of RT-102 Key Takeaways



- RT-102 was well tolerated with repeat dosing
- No SAEs were reported in the study
- Device remnants were eliminated without sequelae in all subjects



- RT-102 RaniPill delivered PTH with reliability of >90%
- Device performance was unaffected by presence of food



- Cmax comparable to SC Forteo
- No accumulation of PTH observed

Next Steps Talat Imran, CEO



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Next Steps and Upcoming Potential Milestones

- Pre-IND meeting request
- Conduct 28-day GLP study
 - Early 2023
- Initiate Phase 2 Study
 - 2H 2023
- Plan to publish RT-102 Phase 1 Study results
- Additional 2023 prospective milestones:
 - Initiation of a Phase 1 study of RT-111 containing an ustekinumab biosimilar
 - Initiation of a Phase 1 study of RT-105 containing an adalimumab biosimilar
 - Initiation of a Phase 1 study of RT-110 containing PTH for hypo-parathyroidism



Appendix

Study Demographics

	Total Cohort (N=17)		Completed Dosing (N=10)	
	Healthy Women	Post-menopausal	Healthy Women	Post-menopausal
	N=11	N=6	N=5	N=5
Age	28 years (22 - 49)	58.8 years (53 - 65)	25.6 years (22 - 35)	60 years (54 - 65)
Race	% (n/N)	% (n/N)	% (n/N)	% (n/N)
Hispanic	18.2 (2/11)	0 (0/6)	20 (1/5)	0 (0/5)
White-non-hispanic	45.4 (5/11)	100 (6/6)	20 (1/5)	100 (5/5)
Asian	11.8 (2/11)	0 (0/6)	40 (2/5)	0 (0/5)
Asian-Pacific Islander	11.8 (2/11)	0 (0/6)	20 (1/5)	0 (0/5)
	Mean ± SD (Min - Max)	Mean ± SD (Min - Max)	Mean ± SD (Min - Max)	Mean ± SD (Min - Max)
Weight (kg)	62.2 ± 8.7 (50.2 - 77.6)	63.7 ± 9.2 (55.6 - 75.4)	60.6 ± 9.8 (50.2 - 76)	64.3 ± 10.1 (55.6 - 75.4)
Body Mass Index (kg/m²)	24.2 ± 2.6 (20.4 - 29.9)	24.8 ± 4.7 (20.9 - 31.7)	23.7 ± 2.5 (20.4 - 26.9)	25.3 ± 5 (20.9 - 31.7)

Adverse Events

	Adverse Event	All Enrolled Participants (N=17)	Participants Completed 7 days (N=10)
PTH-related	Constipation*	1 (5.9%)	1 (10%)
	Diarrhea*	1 (5.9%)	1 (10%)
	Headache	1 (5.9%)	0
RaniPill-related	Abdominal Pain	2 (11.8%)	1 (10%)
	Burping	1 (5.9%)	0



Data from Part 2 of the Phase 1 study of RT-102.

* Same subject reported both AEs on different days

Device Performance with Repeat Doses

Data from 10 participants who completed the 7-day repeat-dosing

Drug signal detected in 63 out of 69 deployments* **At least 91% Success Rate**

Data from all 17 participants

Drug signal detected in 82 out of 93 deployments* **At least 88% Success Rate**

*Deployment confirmed by imaging but not tracked
Samples taken at 3 hr. intervals post-dose
Some misses could be due to mismatch of sampling and deployment time