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): September 07, 2023

Rani Therapeutics Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-40672**	**86-3114789**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer 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:

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 September 7, 2023, Rani Therapeutics Holdings, Inc. (the "Company" or "Rani") issued a press release to announce drug delivery results from three preclinical studies of its high-capacity device for the oral delivery of biologics and drugs. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company is also making available 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 attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release dated September 7, 2023
99.2	Presentation dated September 2023
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: September 7, 2023

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

Exhibit 99.1

Rani Therapeutics Announces Successful Drug Delivery of High-Capacity Pill in Preclinical Studies

- Two preclinical studies of RaniPill® HC achieved 18/20 successful drug delivery of orally administered teriparatide resulting in a cumulative 90% success rate

- Rani will continue preclinical testing to confirm preliminary reliability rate and optimize device performance

- Increased payload of up to 20mg enables potential delivery of 90+ additional drug candidates -

SAN JOSE, Calif., September 7, 2023 -- 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 three new positive preclinical studies which support the development of a high-capacity oral biologics device known as the RaniPill® HC, a version of the RaniPill® capsule that is capable of delivering up to a 500%-plus higher drug payload than Rani’s existing oral biologics capsule.

“We are delighted to share that the orally administered RaniPill® HC was able to demonstrate successful drug delivery and high reliability across multiple preclinical studies, further supporting our development of the RaniPill® HC,” said Talat Imran, Chief Executive Officer of Rani. “The RaniPill® HC is designed to enable the potential delivery of 90+ additional drug candidates, opening up a significant market opportunity for Rani Therapeutics. We are excited about the difference the RaniPill® HC could make to alleviate the burden of painful injections for patients and provide a new solution for providers, and look forward to bringing the technology into the clinic through the initiation of a Phase 1 study of adalimumab RT-105.”

Preliminary Data Highlights:

Teriparatide Canine Studies

Rani conducted two preclinical studies of the RaniPill® HC containing 40ug of teriparatide. In the first study, two RaniPill® HC capsules were orally administered to 5 awake canine subjects sequentially, with a second RaniPill® HC capsule administered after the deployment of the previous device was confirmed. In the second study, a single RaniPill® HC capsule was administered to 10 awake canines.

- RaniPill® HC achieved 18/20 successful drug delivery of teriparatide in the two studies, resulting in a cumulative 90% success rate.
- Successful drug delivery was confirmed by positive drug signal for teriparatide in serum.
- Devices used in these studies were separate iterations, and may not comprise all the same components expected in a final version.
- Preliminary preclinical testing supports the potential for RaniPill® HC to have high reliability.

Fe57 Canine Study

Rani also conducted an additional preclinical study of RaniPill® HC containing Fe57 (iron) in 2 canine subjects.

- The RaniPill® HC containing Fe57 showed a positive drug signal comparable to subcutaneous injection.
- Initial analysis of drug delivery via the RaniPill® HC shows a potential for mimicking parenteral (subcutaneous) administration.

Anticipated Next Steps & Milestones:

- Continue preclinical testing of the RaniPill® HC to confirm the preliminary reliability rate and optimize device performance.
- Introduce RaniPill® HC into the clinic with the initiation of a Phase 1 trial of RT-105 containing adalimumab.

About 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 is progressing two RaniPill® capsules, the RaniPill® GO and the RaniPill® HC. 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.

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 potential initiation of a Phase 1 trial of RT-105, Rani’s development and advancement of its RaniPill® HC and RaniPill® GO capsule technology, the ability to confirm reliability and optimize performance of the RaniPill® HC, the market opportunity for Rani utilizing the RaniPill® HC including the potential to enable Rani to address 90+ additional product candidates, customer acceptance of the RaniPill® capsule technology, the potential benefits of the RaniPill® capsule technology, 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 “could,” “look forward,” “potential,” “enables,” “designed to,” “continue,” “anticipated,” “expected” 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 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

Rani Therapeutics Corporate Presentation

September 2023

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 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, timing of clinical trial initiation for our pipeline programs, achievement of milestones with respect to our pipeline programs, the risks and uncertainties in commercialization and gaining market acceptance, the commercial potential of oral biologics and in particular our core pipeline, our ability to expand use of RaniPill devices to new therapeutic areas or molecules, 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 potential business disruptions such as 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 Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 22, 2023, 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," "look forward," "will" or "would," or the negative of these terms or other comparable terminology. Investors are cautioned that such statements, including, without limitation, those regarding: the progress and focus of our current and future clinical trials, potential of our platform technology, expected pipeline development milestones, and potential addressable markets for our technology and other statements that are not historical facts, constitute forward-looking statements. 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 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. Footnotes are consolidated on a slide at the end of the presentation.

Talat Imran
Chief Executive Officer

Svai Sanford
Chief Financial Officer

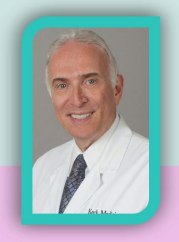
Mir Hashim, Ph.D.
Chief Scientific Officer

Kate McKinley
Chief Business Officer

Eric Groen
General Counsel

Arvinder Dhalla, Ph.D.
Vice President, Clinical Development

Betsy Gutierrez
Vice President, Quality



Jacques Van Dam, M.D.
Vice President, Medical Affairs

Rani Therapeutics is a public, clinical stage biotech company developing a platform technology for the oral delivery of biologic drugs.

Rani Is Pioneering Oral Biologics with Potential Best In Class Technology

True Platform Technology

- Delivery mechanism has potential to deliver a wide range of biologics / large molecules
- Has demonstrated successful delivery of antibodies, peptides, proteins, and other large molecules

Bioavailability

- Demonstrated bioavailability comparable to or better than subcutaneous injection
- Flexibility to titrate doses and dosing schedules to provide for optimum clinical efficacy

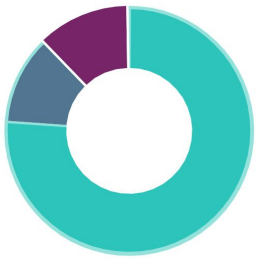
Ahead of Other Oral Devices

- Potential first in class and best in class oral delivery device platform with the most clinical data
- Approaching Phase 2 clinical trials while most competitors are still in preclinical / benchtop testing

Rani's Technology and Approach Is a Potential Breakthrough For The Oral Delivery of Biologics

Substantial Unmet Need for Oral Administration of Biologics

Patients prefer daily pill over current injection regimen



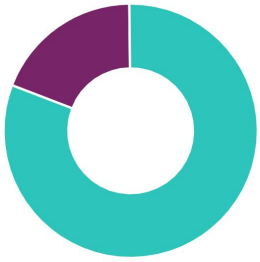
76% of patients with injection regimen of **every 6 months** [1]

88% of patients with injection regimen of **every 2 weeks** [2]

Inconvenience impacts treatment adherence

38% of patients who self administer injections said they **frequently skip doses** [3]

Therapies could start earlier with an oral alternative



81% of endocrinologists would initiate basal insulin therapy earlier with an oral option [3]

Rani is Developing an Oral Delivery Platform to Address this Unmet Need

Rani's Approach:

Opportunity

- Combine the efficacy of biologics with the convenience of small molecules

Best Therapeutic + Best Delivery

Strategy

- Drive internal pipeline programs forward to unlock value of assets and advance platform development
- Actively pursue partnering the technology with valuable third-party assets through licensing and program development

Value

- **Novel Programs:** Potential to create significant advantage for novel assets with differentiated and potentially superior product
- **Life Cycle Management:** Potential to expand market / create meaningful new opportunity for already approved molecules while extending patent protection

Rani THERAPEUTICS

Partnered with Celltrion On Two Important Assets

Ustekinumab Biosimilar (RT-111)

- **Lead Indication:** Psoriasis
- **Market Size:** $9.7B in Stelara® (ustekinumab) sales in 2022 [4]

Adalimumab Biosimilar (RT-105)

- **Lead Indication:** Psoriatic Arthritis
- **Market Size:** $21.2B in Humira® (adalimumab) sales in 2022 [5]

CELLTRION

- Combining proven, high value drugs with competitive and disruptive technology
- Two partnerships that validate the RaniPill platform

Potential to Disrupt Billion-Dollar Markets with First Oral Option for Biologic Therapies in Psoriasis and Psoriatic Arthritis

Productive Pipeline Across a Variety of Therapeutic Areas

PROGRAM	INDICATION	FORMULATION	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT EXPECTED MILSTONE*
Core Programs							
RT-102	**Osteoporosis**	**PTH-OP**					Initiate Phase 2 in 2023
RT-111	**Psoriasis**	**Ustekinumab****					Initiate Phase 1 in 2023
RT-105	**Psoriatic Arthritis**	**Adalimumab****					Initiate Phase 1
RT-110	**Hypo-parathyroidism**	**PTH - Hypo**					Initiate Phase 1
RT-101	**NETs / Acromegaly*****	**Octreotide**					Optimizing formulation

RT-XXX refers to the RaniPill capsule containing a biologic in a proprietary Rani formulation
* Clinical timelines are subject to potential regulatory agency review delays
** Partnered with Celltrion, Inc. Celltrion grants Rani a license and drug supply for the drug and has a right of first negotiation following Phase 1.
*** Each of these indications will require separate trials.

Robust Database to Support Our Technology

Preclinical

14 Molecules Assessed
antibodies, peptides, and large proteins

>6800 Capsules
tested *in vitro & in vivo*

3 Pharmacodynamic
studies conducted

Clinical

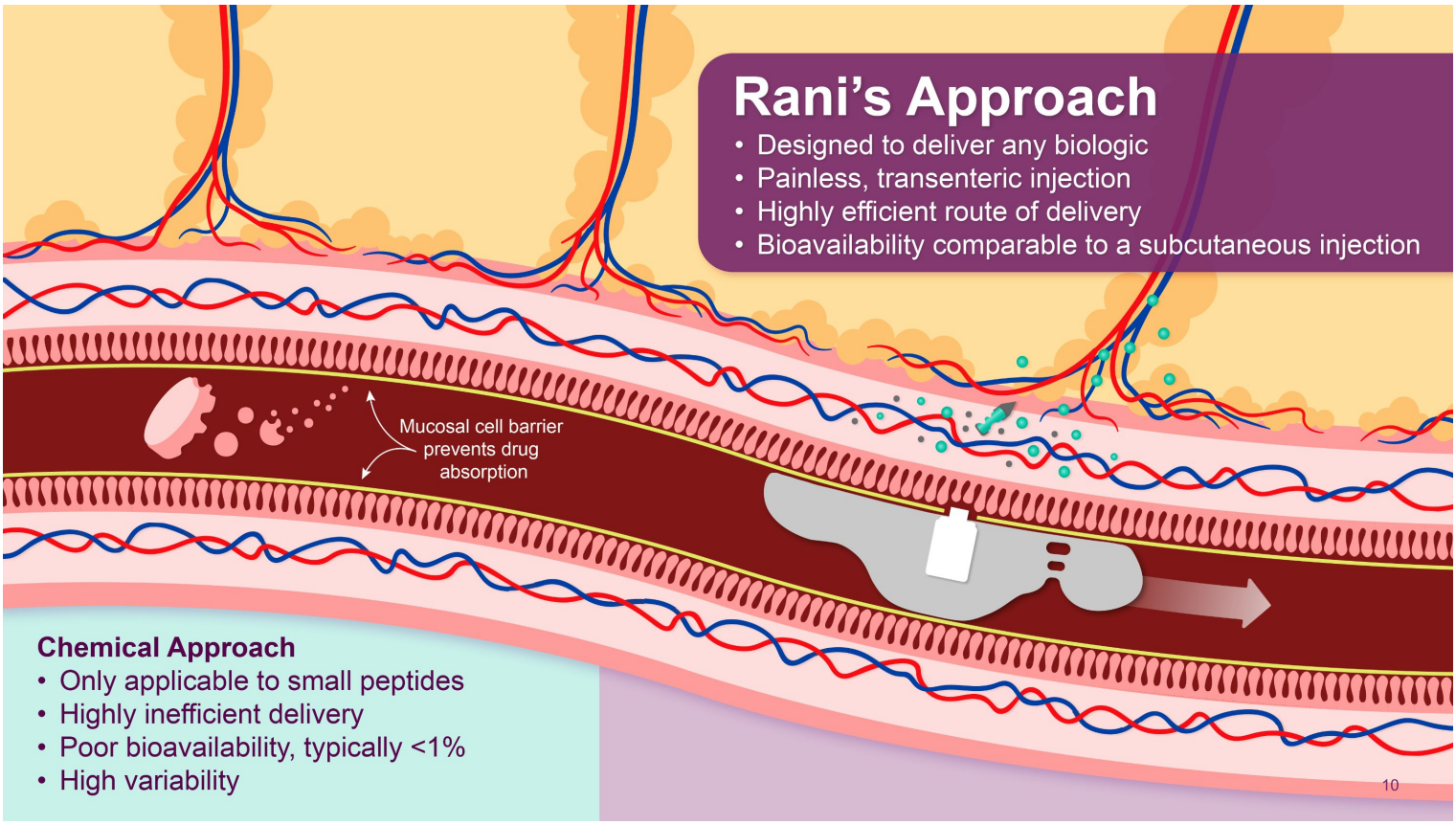
2 Phase I Studies
completed

193 RaniPill Capsules
administered in 106 humans*

Repeat Dose Study
completed

* As of 8/1/23

Well-Tolerated with No Serious Adverse Events Observed in Clinical Studies to Date


Rani's Approach
• Designed to deliver any biologic
• Painless, transenteric injection
• Highly efficient route of delivery
• Bioavailability comparable to a subcutaneous injection
Mucosal cell barrier prevents drug absorption
Chemical Approach
• Only applicable to small peptides
• Highly inefficient delivery
• Poor bioavailability, typically <1%
• High variability
10

Rani Platform has Clinically Demonstrated Tolerability and Favorable Safety Profile

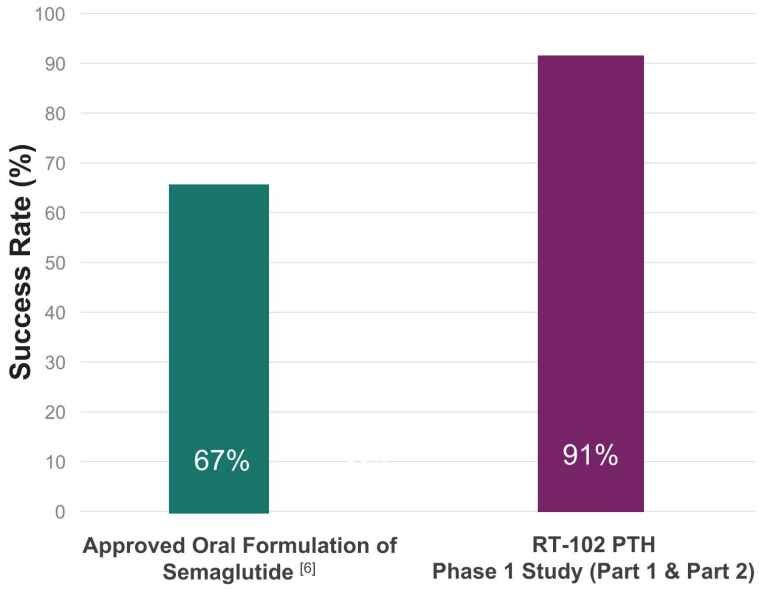
In two Phase 1 studies:

- ✓ RaniPill was well-tolerated
- ✓ No serious adverse events

Adverse Events	All RaniPill-related AEs from Subjects Completing RaniPill Arms of Phase 1 studies (N=91)
Transient Abdominal Pain*	2 (2%)
Burping**	1 (1%)

* Abdominal pain classified as mild
** Burping lasted 2 days and was classified as moderate

RaniPill Has Demonstrated High Reliability in Clinical Studies



90% success rate means the chance of consecutive failures in a daily dosing regimen is less than once per quarter

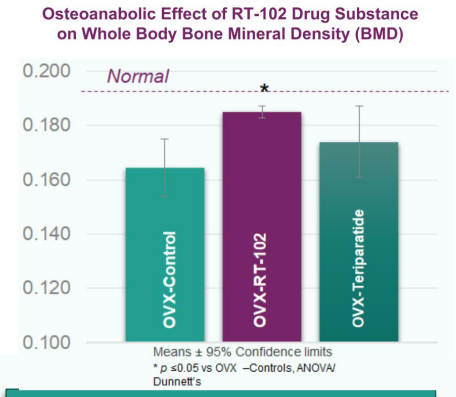
Robust patent portfolio with over 425 patent applications filed and 225 patents granted**

* Data not from head-to-head study
** As of 12/31/22

RT-102 Phase 1 Study Demonstrated Drug Delivery Reliability Greater than Delivery Reported in Single-Dose Trial of Currently Approved Product*

Demonstrated Biologic Activity in Preclinical Pharmacodynamic Studies

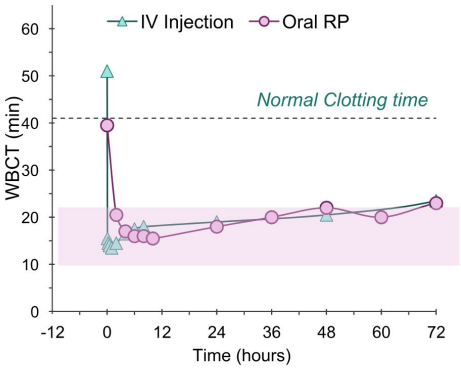
Teriparatide (RT-102) Increased Bone Mineral Density in Rat Osteoporotic Model



IP Delivery (to mimic RaniPill delivery) for 6 weeks Increased BMD in Ovariectomized Rats Comparable to SC Teriparatide Injections

Daily dosing for 6 weeks of saline (control) or drug; N=10 per group
* IP delivery is intraperitoneal delivery

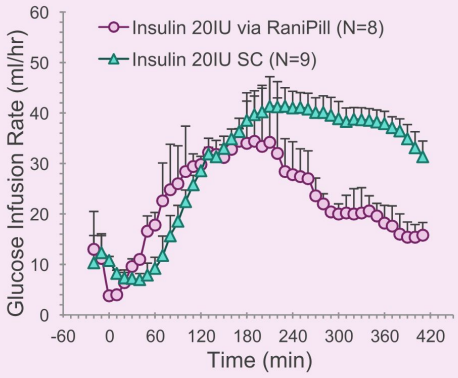
Factor VIII (RT-108) Normalized Coagulopathy in A Canine Model of Hemophilia A



A Single Oral RaniPill Normalized the Coagulopathy for 3 Days Comparable to the Same Standard IV Dose

Single dose of 150IU/kg (RP or IV)
N=1 per group

Insulin (RT-104) Induced Rapid Glucose Disposal in Swine Under a Euglycemic Clamp

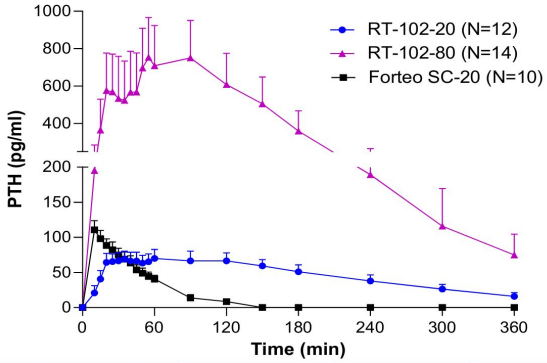


RT-104 Elicited More Rapid Glucose Disposal than SC Dose

Pipeline Programs

RT-102: Positive Phase I Data for Osteoporosis

PK Profiles of Single Doses of RT-102



PK Parameters	Forteo SC 20µg	RT-102 20µg	RT-102 80µg
Cmax (pg/mL)	128 ± 64	98 ± 35.5	971 ± 826
Tmax (minutes)	13	68	60
AUC (pg*h/mL)	126 ± 91	343 ± 123	2600 ± 2410
Relative BA (%)		~300%	~400%

Safety & Tolerability:

- ✓ RT-102 was well-tolerated
- ✓ Completed 7-day repeat dosing
- ✓ No serious adverse events

Milestones & Anticipated Next Steps:

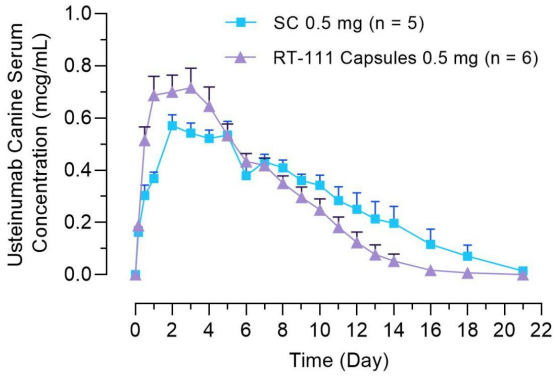
- ➢ Presented at ENDO 2023
- ➢ Initiate Phase 2 Study in 2023

Rani THERAPEUTICS

RT-102 Phase 2 Trial Expected to Initiate in 2023

- **Study Design:** Phase 2, open-label, dose-finding study of RT-102
- **Dosing Arms:**
  - Forteo SC 20 µg dose (N=25)
  - RT-102 20 µg dose (N=25)
- **Patient Population:** Postmenopausal women with osteoporosis
  - defined as BMD T-score ≤-2.5 and ≥-4.0 at either the lumbar spine (L1-L4), femoral neck, and/or total hip, measured by DXA scan
- **Endpoint:** Changes in bone growth biomarkers (P1NP, CTX and Osteocalcin) at 8 weeks
- **Study Sites:** Eastern Europe (Georgia, Estonia, Romania, Slovakia, and the Czech Republic)

RT-111: Oral Ustekinumab Development



Route	Pharmacokinetic Parameters (Mean ± SEM)		
	C_{max} (µg/mL)	T_{max} (day)	AUC (day. µg/mL)
SC 0.5 mg (n = 5)	0.60 ± 0.05	2.8 ± 0.58	6.01 ± 0.68
RT-111 Capsules 0.5 mg (n=6)	0.75 ± 0.07	2.3 ± 0.3	5.63 ± 0.59

RT-111 Capsules 0.5 mg Showed 94% Relative Bioavailability Compared to SC Injection

- All animals receiving RT-111 in preclinical testing showed successful drug delivery (100% device success rate)

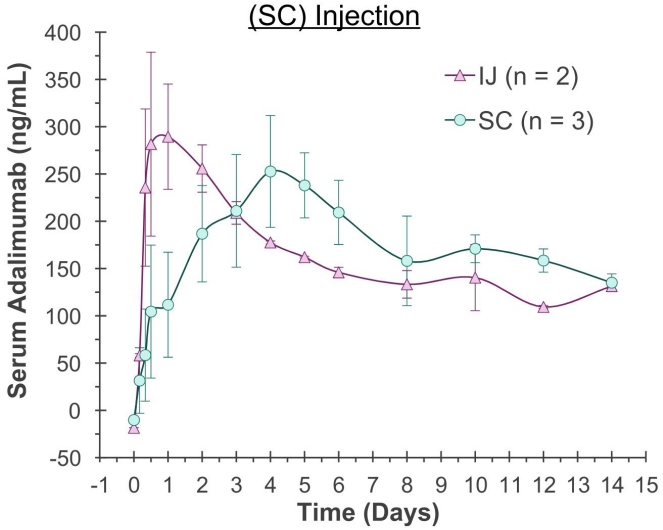
Anticipated **Next Steps:**

- On track to begin Phase I trial in 2023
  - Single dose, healthy volunteers
  - Testing doses of 0.5 and .75 mg

Rani THERAPEUTICS

RT-105: Oral Adalimumab Development

Human PK Data of Adalimumab (2.5mg): Endoscopic Injection (IJ)* vs. Subcutaneous (SC) Injection



* IJ route mimics Rani route of administration

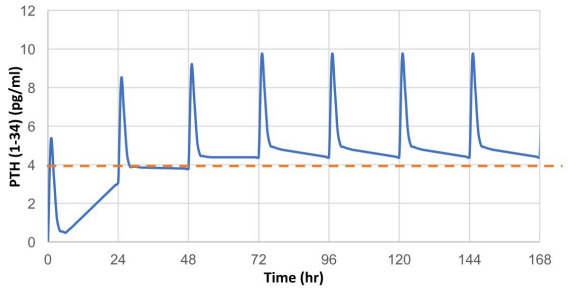
Adalimumab Delivered via the RaniPill Route of Administration Demonstrated PK Comparable to SC Injection

Anticipated Next Steps:

- Begin Phase I trial with RaniPill HC

RT-110: Oral Long-Acting PTH for Hypoparathyroidism

Rani Long-Acting PTH Formulation Repeat Dose Simulation Based on Early PK



Physiological PTH (1-34) = 4-26 pg/ml

Long-acting formulation extends PTH serum concentrations up to 72 hours

Daily dosing simulation shows that preclinical data generated with RT-110 can achieve steady-state within the defined therapeutic window for hypoparathyroidism patients

Hypoparathyroidism Market Opportunity:

- Significant unmet medical need
- Conventional therapy aimed at short-term symptom management with large doses of oral calcium and active vitamin D as first-line therapy option
- Market forecast to reach $2.64B by 2030 [7]
- All other long-acting PTH formulations currently under development are daily injections

RT-110 Could Be a Significantly Differentiated Product in This Therapeutic Landscape

Discovery Programs

Strategic Focus Areas

Actively Investigating Through Preclinical Work:

Initial Focus:
Endocrinology & Immunology

- Proteins
- Peptides
- Antibodies

$50BN+*
initial market opportunity **based on core pipeline programs**

Obesity / Metabolic Diseases

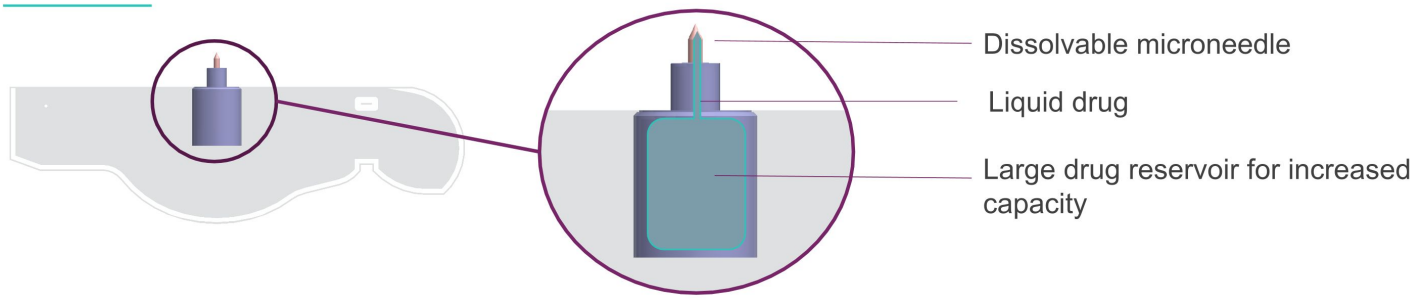
Oligonucleotides

Fertility

* Includes third-party estimates of global TNFa inhibitors market (all indications) in 2021, global octreotide market in 2022, global parathyroid hormone market in 2022, and reported global sales of Stelara in 2022.

Our Technology is Designed to Enable a Broad Set of Opportunities for Asset Development

RaniPill HC (High Capacity) Expands the RaniPill Platform



Increased Payload of Up to 20mg

- Enables potential delivery of 90+ additional drug candidates including:

Keytruda (pembrolizumab) Herceptin (trastuzumab) Cosentyx (secukinumab)
Dupixent (dupilumab) Enbrel (etanercept)

Transenteric Delivery of Liquid Drug

- Minimizes formulation steps required

Leverages Common Components and Manufacturing Processes from RaniPill GO

Rani THERAPEUTICS

* Device design shown for illustrative purposes only; actual design may differ

Recent Preclinical Studies* of RaniPill HC Achieved 18/20 Successful Deployments of Teriparatide in Awake Canines

Endpoint: Successful drug delivery confirmed by positive drug signal for teriparatide

Study #1: Two RaniPill HC capsules containing 40µg teriparatide were administered to 5 awake canines sequentially (second capsule administered after deployment of previous device was confirmed)

→ 10/10 Successful deployments were confirmed resulting in a 100% success rate

Study #2: RaniPill HC capsule containing 40µg teriparatide was administered to 10 awake canines

→ 8/10 Successful deployments were confirmed resulting in an 80% success rate

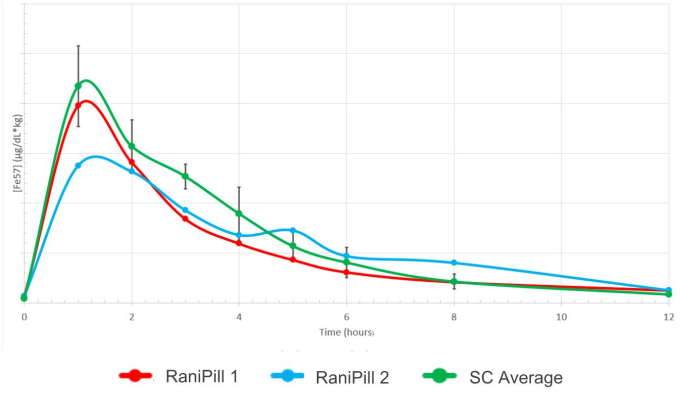
Cumulative Success Rate Across Two Preclinical Studies = 90%

* Devices used in these studies were separate iterations, and may not comprise all the same components expected in a final version.

Preliminary Preclinical Testing Supports Potential for RaniPill HC to Have High Reliability

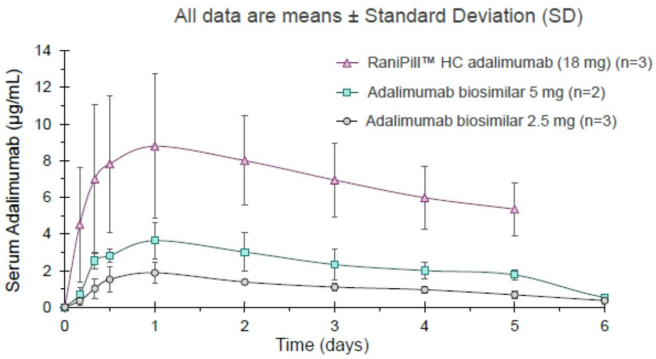
RaniPill HC Shows Drug Signal Comparable to SC Injection*

Fe57 Delivered Via the RaniPill HC in Awake Canines



- RaniPill HC Containing Fe57 Showed Positive Drug Signal Comparable to SC Injection

PK Curves of Adalimumab ~18 mg delivered via RaniPill HC and Historical RaniPill Data with Adalimimab Biosimilar in Awake Canines



- The PK curves indicate linear, dose-dependent increases in drug exposures

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Initial Analysis of Drug Delivery Via the RaniPill HC Shows Potential for Mimicking Parenteral Administration Routes

RaniPill HC Development On Track with Positive Preclinical Results

Preliminary Data*

- Two Recent Preclinical Studies Showed 18/20 Successful Drug Delivery (90% Success Rate)
- RaniPill HC Preclinical Study of N=2 Containing Fe57 Showed Positive Drug Signal Comparable to SC Injection

Next Steps & Anticipated Milestones

- Continue Preclinical Testing to Confirm Preliminary Reliability Rate and Optimize Performance
- Introduce RaniPill HC into the Clinic with RT-105, Oral Adalimumab

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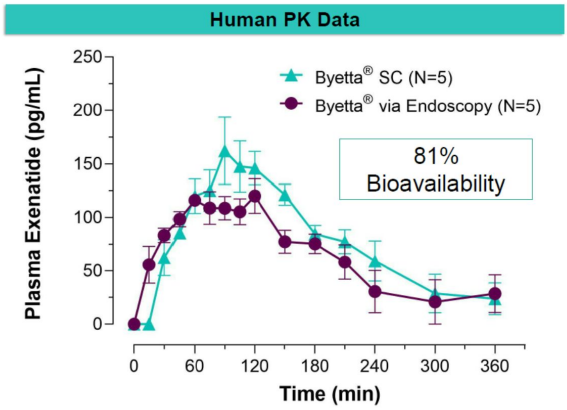
Obesity/Metabolic: GLP-1 Clinical Study

Rani has demonstrated high bioavailability of the GLP-1 agonist exenatide



- Presented as a late-breaking abstract at the American Diabetes Association Conference 2023

Key Drivers:

- Large and growing patient population seeking treatment options for obesity
- Approved therapies for obesity are non-ideal
  - Majority of obesity treatments are monthly or weekly injectables
  - Low bioavailability leading some to explore extremely high dosing (up to145x SC dose [8])
  - Small molecules unlikely for multi-agonist approach

Rani Strategy:

- Target 25% reduction in weight with multi-agonist
- Dosing flexibility
  - Convenience of QW dosing
  - Fractionated QD dosing with potentially improved tolerability

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Oligonucleotides: Preliminary Research with ASO

- ASO administered via endoscopic injection that mimics RaniPill route of administration
- PK profiles for Rani route of administration and SC administration were comparable

Key Drivers:

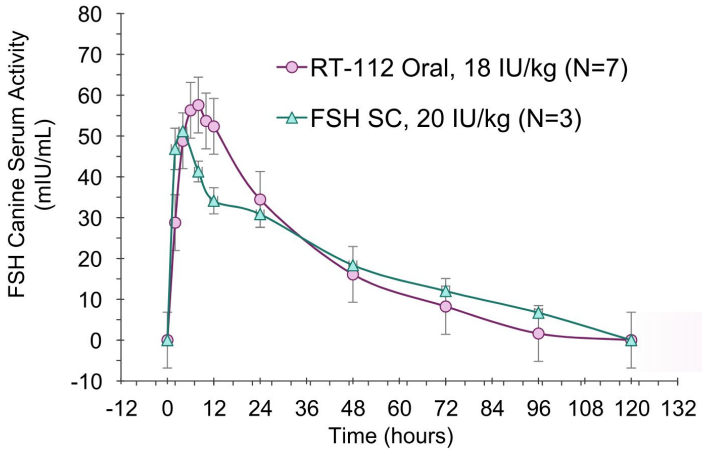
- Emerging area of drug development that offers a promising alternative to therapies targeting downstream processes
- Chemistry attempts at oral delivery have had mixed results in terms of bioavailability

Rani Strategy:

- Provide a safe and efficacious way to deliver ASOs orally
- Some prior oral administration attempts have shown five-fold increase in liver concentration.[9] Rani could potentially couple this with serum bioavailability equivalent to SC injection

Fertility: FSH Preclinical Study

FSH delivered via the RaniPill Yielded Bioavailability Comparable to SC Injection



Key Drivers:

- Market Poised for significant growth:
  - IVF services estimated at $3B market and projected to grow at a 10% rate through 2024 [10]
  - Between 2009 and 2016, number of women in the US who froze their eggs rose by more than 1,000% [11]
- Cash pay for high-cost treatment
- 7–14-day treatment
- Burdensome and difficult to administer injections

Rani Strategy:

- Provide oral option to expand market opportunity even further with minimal manufacturing burden

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Anticipated Upcoming Milestones & Progress

- Initiate a Phase 2 clinical trial with RT-102 in 2023
- Initiate a Phase 1 clinical trial with RT-111 in 2023
- Progress development of RaniPill HC towards clinic
- Evaluate platform further in strategic areas of focus

The RaniPill is Reinventing the Oral Delivery of Biologics

Clinically Demonstrated Bioavailability Comparable To or Better Than Approved Injectable Biologics

- Peptides
- Monoclonal Antibodies
- Hormones
- Large Proteins

Best Therapeutic + Best Delivery

Potential for Wide Range of Biologic Therapies to be Put into a RaniPill

- ☑ Platform Technology
- ☑ Robust Database
- ☑ Differentiated Product
- ☑ Patients Prefer Orals

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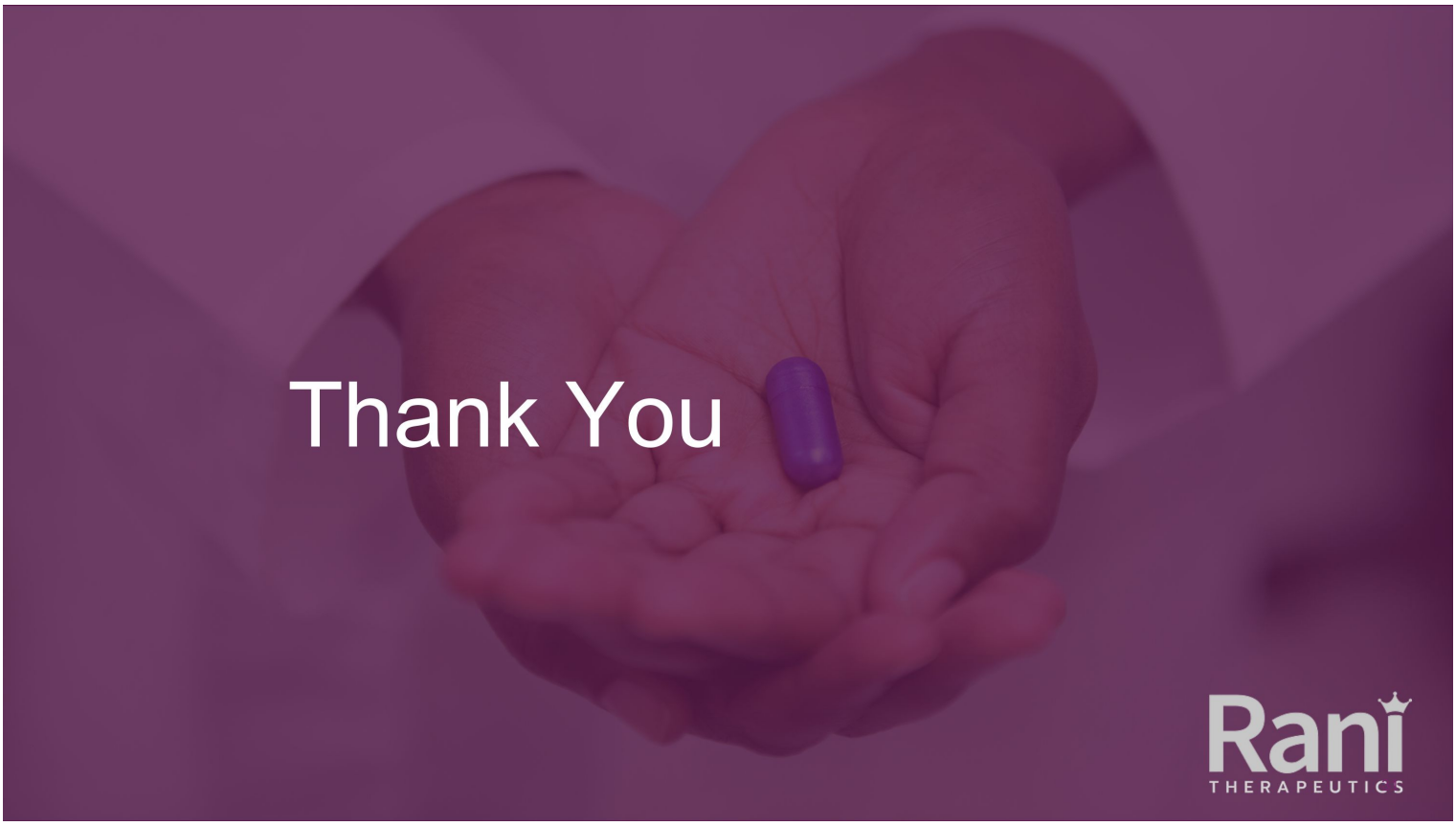

Thank You
Rani
THERAPEUTICS

Appendix

RT-102 Market opportunity

Oral PTH (1-34) for Treatment of Osteoporosis

Significant opportunity for an oral parathyroid hormone option for patients with osteoporosis

- Current anabolic (bone forming) therapies require daily or monthly injections

1.5 million fractures in the US related to osteoporosis yet fewer than 20% of women receive treatment for osteoporosis – even after breaking a bone [12]

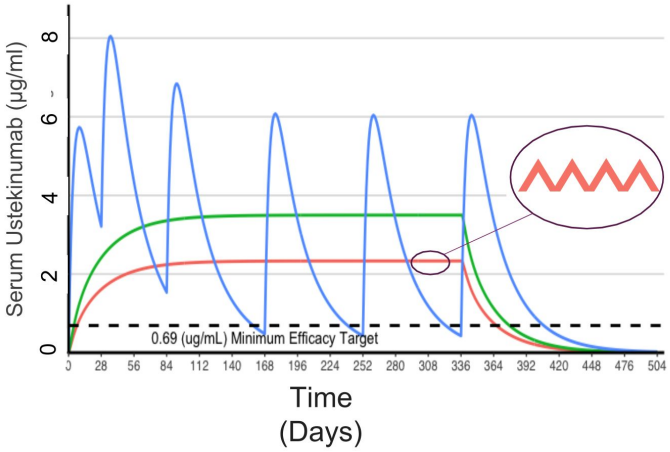
- Oral option addresses injection aversion
- Potential to grow market with earlier intervention with an oral option

Global PTH market expected to grow to $2.51B in 2026 at CAGR of 4% [13]

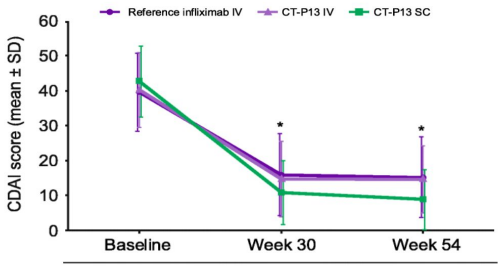
- Forteo (teriparatide) earned $613M in revenue in 2022 [14]

Daily Dosing Has the Potential for Positive Clinical Impact

Actual data from 45mg SC injections of ustekinumab every 12 Weeks vs simulated data for Daily Doses of 0.5mg or 0.75mg



Celltrion infliximab subcutaneous **Q2W*** vs. IV administration **Q8W***[15]



	Mean change from baseline at Week 30	Mean change from baseline at Week 54
Reference infliximab IV	–23.77	–24.08
CT-P13 IV	–25.52	–25.52
CT-P13 SC	–31.89	–34.09

Increased frequency showed significant association between **improved clinical response with higher trough serum infliximab levels**

Daily Administration of Fractionated Doses Enables Tight Banding and Titration for More Controlled and Potentially More Effective Treatment Regimens

Financing & Shareholdings

Umbrella Partnership C Corporation (Up-C)

Rani Therapeutics Holdings, Inc.
(PubCo - Parent Company)

"Class A Shares" Common Stock
"Class B Shares" Common Stock

*Holders of interests in Rani Therapeutics, LLC can exchange those interests (together with their Class B shares) for an equal number of shares of Class A common stock

Insiders own 48% of Class A shares on "as exchanged" basis as of 6/30/23

Rani Therapeutics, LLC*
(Subsidiary)

1 Class A unit LLC + Class B common = "paired interest" = 1 Class A common [1:1 conversion]
1 non-corresponding Class A unit LLC = 1 Class A common [1:1 conversion]

Financing History

AUGUST 2021 - IPO
$ 84.3 million gross proceeds
Rani THERAPEUTICS
Bank of America Stifel Cantor Fitzgerald & Co. Canaccord Genuity
BTIG

AUGUST 2022 – ATM Controlled Equity℠ Sales Agreement
$Up to $150 million [not utilized to date]
Rani THERAPEUTICS
Cantor Fitzgerald & Co. H.C. Wainwright & Co., LLC

AUGUST 2022 - LOAN
Aggregate principal amount up to $45.0 million; $30M drawn to date
Rani THERAPEUTICS
Avenue Capital

To date, Rani has financed its operations primarily through an IPO, private placements and long-term debt, as well as contract revenue generated from evaluation agreements

References

[1] Survey of U.S. Clinicians and Patients on Adoption of Novel Oral Drug Delivery Platform dated June 2, 2021, Frost & Sullivan. The independent third-party survey was commissioned by Rani Therapeutics. Product referenced is Prolia. Prolia patients surveyed (n=103) were aged 18 years or older and presently used Prolia as an injectable biologic to treat a condition.

[2] U.S. Physician and Patient Assessment of the Rani Therapeutics Platform in Diabetes and Inflammatory Disease dated October 24, 2017, Frost & Sullivan The independent third-party survey was commissioned by Rani Therapeutics. Product referenced is Humira. Humira patients surveyed (n=501) were aged 18 years or older and presently used Humira as an injectable biologic to treat a condition.

[3] U.S. Physician and Patient Assessment of the Rani Therapeutics Platform in Diabetes and Inflammatory Disease dated October 24, 2017, Frost & Sullivan The independent third-party survey commissioned by Rani Therapeutics. Patients surveyed were aged 18 years or older. Two patient groups included 501 patients taking Humira for the treatment of an inflammatory condition and 577 patients taking basal insulin for the treatment of diabetes. Physician group consisted of 61 U.S.-based endocrinologists.

[4] Johnson & Johnson 2022 Annual Report.

[5] Abbvie 2022 Annual Report.

[6] Granhall et al, Clinical Pharmacokinetics (2019) 58:781–791 2019. In single dose study of oral semaglutide, highest percentage of subjects with measurable semaglutide plasma concentrations among dose groups was 66.7% (16/24).

[7] Hypoparathyroidism Treatment Market Report, SNS Insider Strategy & Stats, May 2022.

[8] Knop et al, The Lancet 2023 Jun 23; S01406736(23)01185-6. Study evaluated 50mg/day of oral semaglutide. Wegovy injectable maintenance dose is 2.4mg per week (see Wegovy Prescribing Information).

[9] Genemark et al, *An Oral Antisense Oligonucleotide for PCSK9 Inhibition*, Science Translational Medicine, 12 May 2021, DOI 10.1126/scitranslmed.abe9117.

[10] *What's Next for the Fertility Market?,* EviCore Health, 25 October 2021.

[11] *The Growing Popularity of Egg-Freezing,* Quartz, 8 February 2022.

[12] Boytsov, N. N., et al. (2017). Patient and Provider Characteristics Associated with Optimal Post-Fracture Osteoporosis Management. American Journal of Medical Quality, 32(6), 644–654.

[13] Parathyroid Hormone Global Market Report 2023, The Business Research Company, February 2023.

[14] Eli Lilly and Company 2022 Annual Report.

[15] Combe, B., Allanore, Y., Alten, R., Caporali, R., Durez, P., Iannone, F., Nurmohamed, M. T., Toumi, M., Lee, S. J., Kwon, T. S., Noh, J., Park, G., & Yoo, D. H. (2021). Comparative efficacy of subcutaneous (CT-p13) and intravenous infliximab in adult patients with rheumatoid arthritis: A network meta-regression of individual patient data from two randomised trials. *Arthritis Research & Therapy*, *23*(1). https://doi.org/10.1186/s13075-021-02487-x.