

# Corporate Presentation (RT-102 Data)



August 2022

**Rani**<sup>®</sup>  
THERAPEUTICS

# Forward-Looking Statements

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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, 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](http://www.sec.gov).

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# Corporate Summary

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- Clinical-stage biotherapeutics company seeking to convert injectable biologics and drugs into pills
- **\$56BN+ initial market opportunity<sup>1</sup>** targeting multiple markets across multiple diseases
- 5 internal development programs
- Completed single ascending dose portion of RT-102 (PTH) Phase 1 clinical trial
- Completed RT-101 (octreotide) Phase 1 clinical trial investigating platform safety, tolerability and bioavailability
- Developing new high-capacity RaniPill HC
- Established IP portfolio with 380+ patent applications filed and 220+ patents granted as of 8/1/22

# Agenda

- 01 RT-102 Phase I Study

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- 02 RT-102 Rat PD Study

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- 03 Next Steps

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- 04 RaniPill Platform Opportunity

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- 05 RaniPill Technology Overview

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# RT-102 Phase I Study Design

# Study Overview

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

Objective	To obtain PK profiles of single doses of PTH given via RaniPill capsule (RT-102) in healthy participants at 20 and 80µg doses
Study Population	Healthy women volunteers recruited from the general population
Study Site	Single Site in Australia
End Points	PK parameters, Safety and Tolerability
Start Date	March 2022

# Study Design: Single Ascending Doses\*

## Control Group

- SC Forteo®\*\*: 20µg (N=10)
- PK sampling done for 360 minutes

## RT-102 Groups

- RT-102 Group 1: 20µg (N=15)
- RT-102 Group 2: 80µg (N=15)
- Transit of RaniPill capsule in the GI tract tracked via frequent fluoroscopic imaging and deployment was confirmed before starting PK sampling\*\*\*
- PK sampling done for 360 minutes

\* Part 1 of the Phase 1 study is single-ascending doses. Part 2, involving repeat doses, is ongoing.

\*\* Forteo® is a registered trademark of Eli Lilly and Company.

\*\*\* Per protocol, in instances where RaniPill capsule did not exit the stomach within 7 hours, participants were excluded from the study. Based on the exclusion criteria, 3 participants were excluded from the study. 1 additional subject was excluded due to vomiting the capsule intact.

# Study Results



# Study Demographics

	RT-102 20µg	RT-102 80µg	Forteo SC 20µg
N	15	14	10
Mean Age, years	31.2 (19 - 61)	31.2 (20 - 63)	32.6 (18 - 63)
Race			
White-non-hispanic	80% (12/15)	78.6% (11/14)	50% (5/10)
Hispanic	6.7% (1/15)	0% (0/14)	10% (1/10)
Asian	6.7% (1/15)	7.1% (1/14)	20% (2/10)
Asian-Pacific Islander	0% (0/15)	14.2% (2/14)	20% (2/10)
Pacific Islander	6.7% (1/15)	0% (0/14)	0% (0/10)
Body Mass Index (kg/m <sup>2</sup> )	23.5 ± 3.9	25 ± 3.6	23.6 ± 3.6
Height (cm)	164.3 ± 7.1	164.4 ± 6.27	162.5 ± 7.7
Weight (kg)	63.3 ± 10.9	67.4 ± 10.2	62.4 ± 11.6

BMI, Height and Weight data are Mean ± SD

# Incidence of Adverse Events

	Adverse Events	RT-102 20µg (N=15)	RT-102 80µg* (N=14)	Forteo SC 20µg (N=10)
	All	0	2 (14%)	5 (50%)
Drug-Related AE	Light headedness	0	0	2 (20%)
	Nausea	0	1 (7%)	3 (30%)
	Vomiting	0	1 (7%)	
RaniPill-Related AE		0	0	N/A

No RaniPill-related AEs observed in 81 subjects across two clinical studies  
(RT-101 Phase 1 and RT-102 Phase 1)

# Safety and Tolerability Data

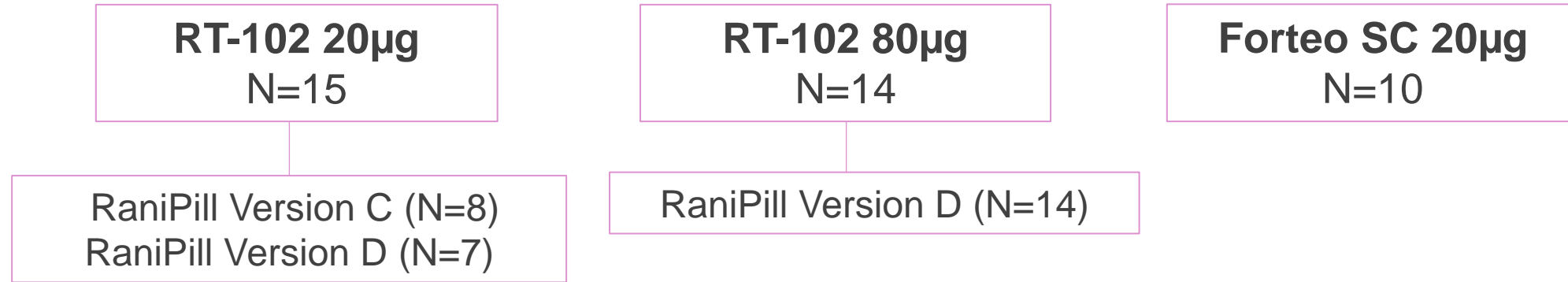
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- RT-102 was generally well-tolerated by all subjects
- No serious adverse events noted in the study
- No subject excluded due to difficulty swallowing the capsule
- Capsule remnants passed out in all subjects

# Device Performance

# Device Versions and Study Groups

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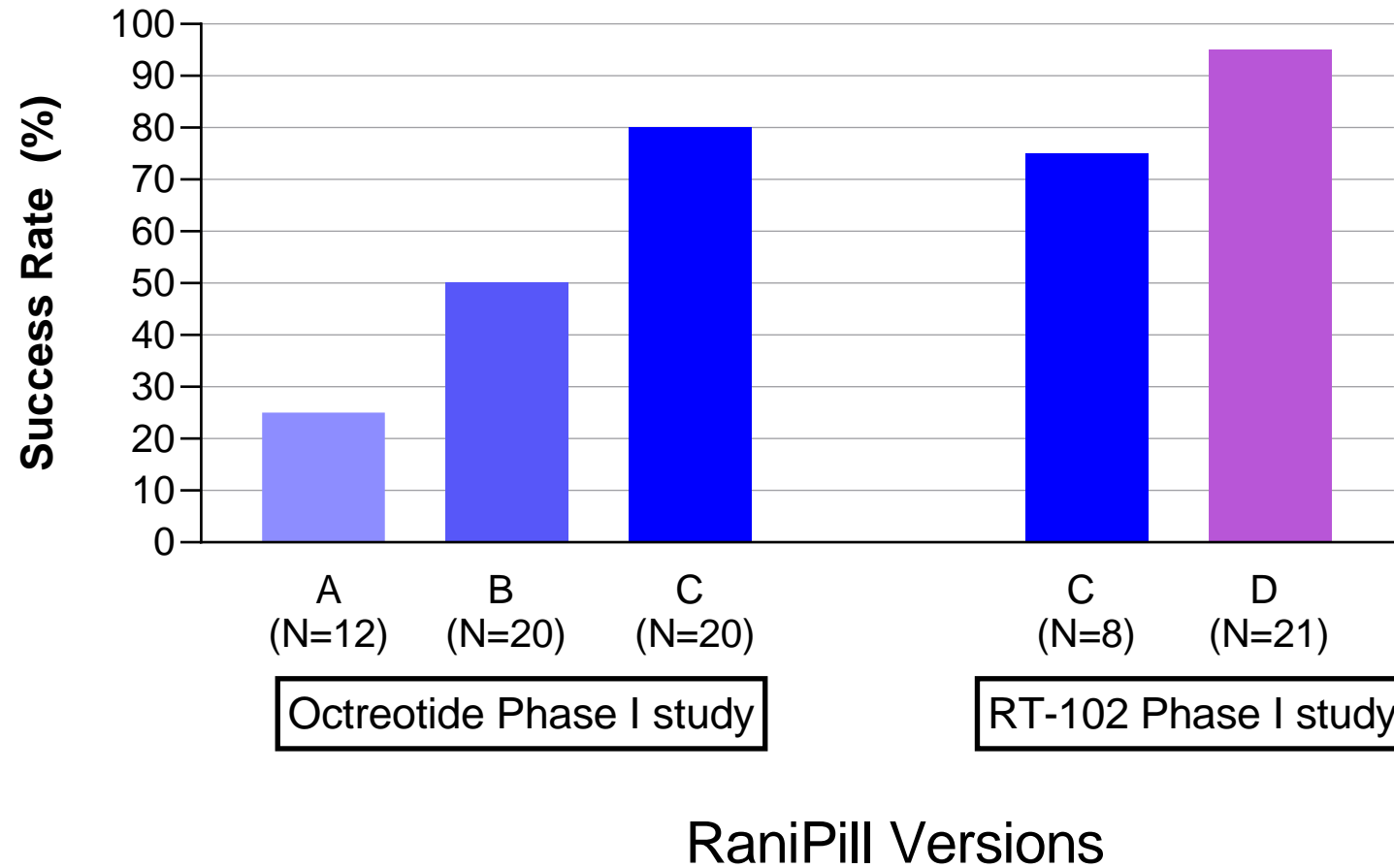
**Final N by Version**  
RaniPill Version C = 8  
RaniPill Version D = 21

# Device Performance

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Group	Successful Drug Delivery (N)	Drug Delivery Success Rate
RaniPill C Previous Version	6/8	<b>75%</b>
RaniPill D New Improved Version	20/21	<b>95%</b>

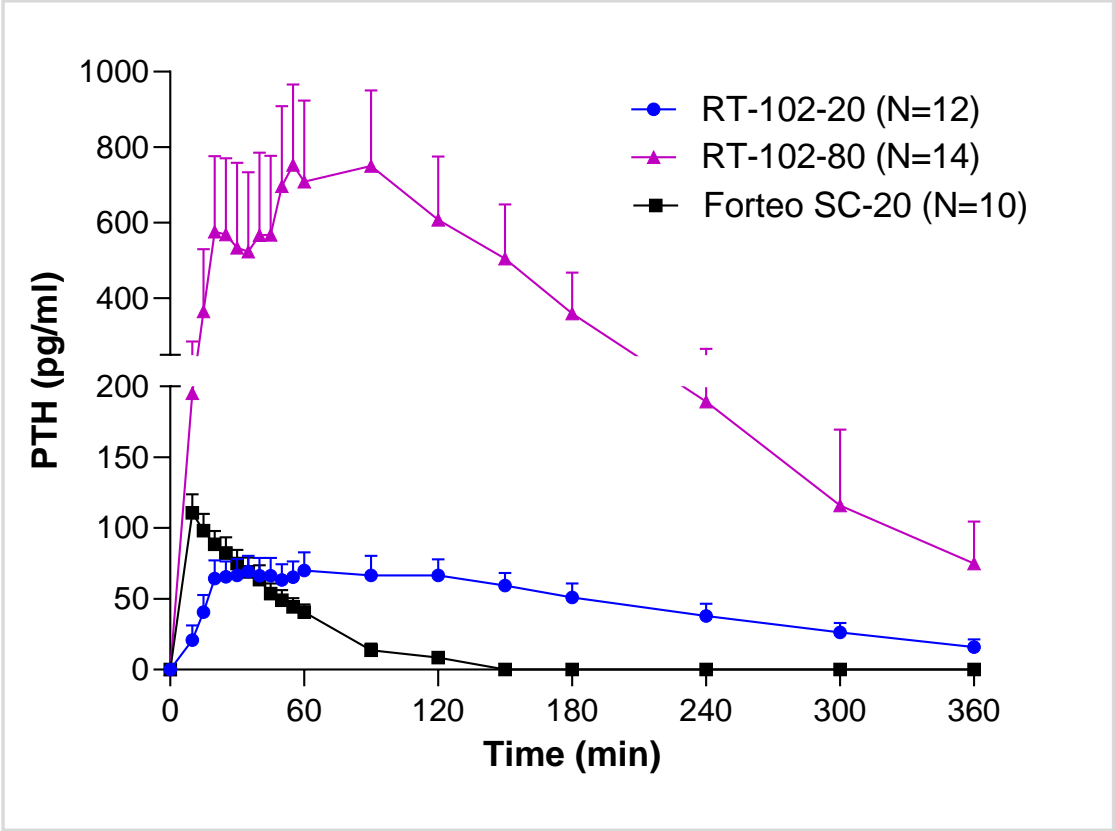
# Device Performance: Progression of Drug Delivery Success Rate



# Pharmacokinetic Data



# RaniPill Delivered PTH with Higher Bioavailability than SC

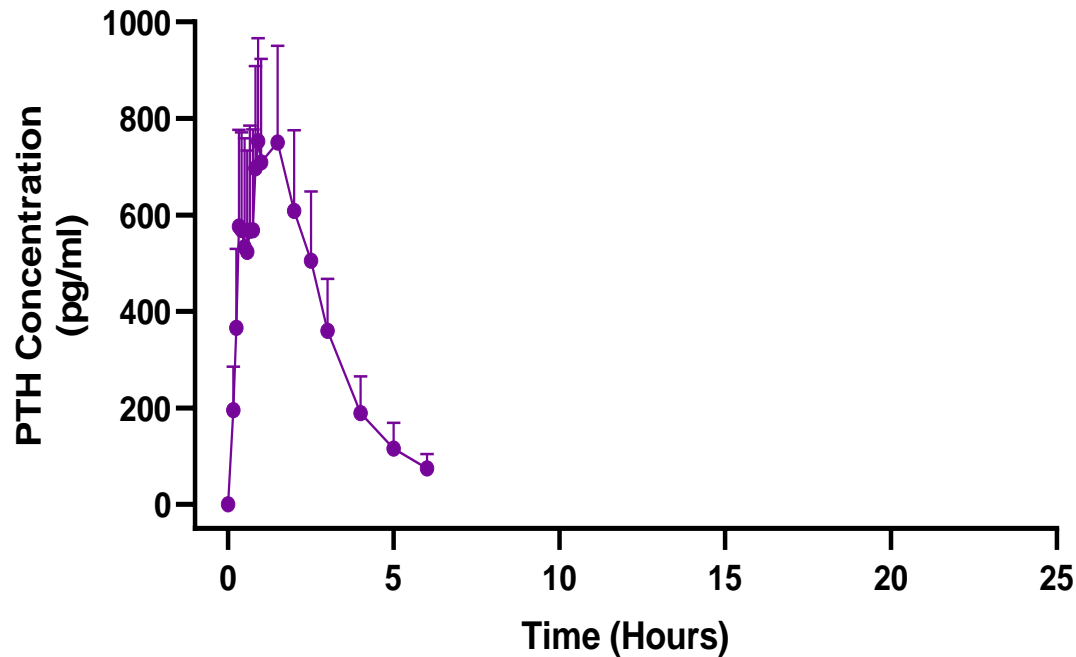


PK Parameters

	Forteo SC 20µg	RT-102 20µg	RT-102 80µg
Cmax (pg/mL)	128 ± 20	98 ± 10	971 ± 223
Tmax (hr)	0.217	1.13	0.994
AUC (h*pg/mL)	126 ± 64	342 ± 36	2600 ± 649
Relative BA (%)		~300%	~400%

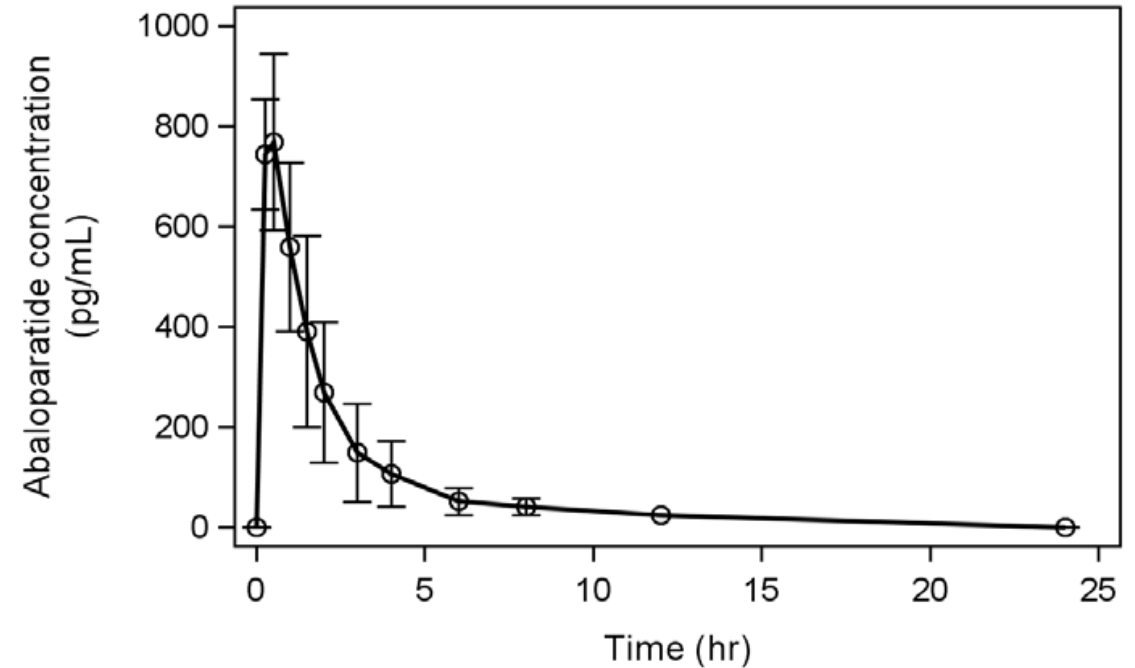
# RT-102 80µg PK Profile is Similar to Tymlos®\* at 80µg\*\*

RT-102 Phase I Data  
Dose 80µg



- $C_{max}$  971 (223) pg/mL
- $AUC_{0-24}$  2600 (649) pg·hr/mL

Tymlos Package Insert  
Dose 80µg



- $C_{max}$  812 (118) pg/mL
- $AUC_{0-24}$  1622 (641) pg·hr/mL

80µg abaloparatide (Tymlos) showed bone mineral density improvements significantly greater than 20µg teriparatide (Forteo) at several bone sites in a Phase 3 study\*\*\*

# Phase I (Part 1) Study Summary

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Adverse events related to  
the RaniPill platform



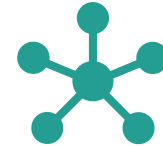
95%

RaniPill platform  
drug delivery  
success rate\*



>300%

RT-102 bioavailability  
compared to SC injection



## RT-102 Expected Next Steps

Phase I part 2: Repeat dose study in progress

Pre-IND meeting in Q4

- Briefing document in preparation
- Submit request in end of Q3

RT-102 Phase II study planned to start Q3 2023\*

- Study protocol in development

\* Subject to submission and FDA clearance of an IND.

# Effect of RT-102 Drug Substance on Bone Growth in a Preclinical Model of Osteoporosis



# Study Objectives and Rationale

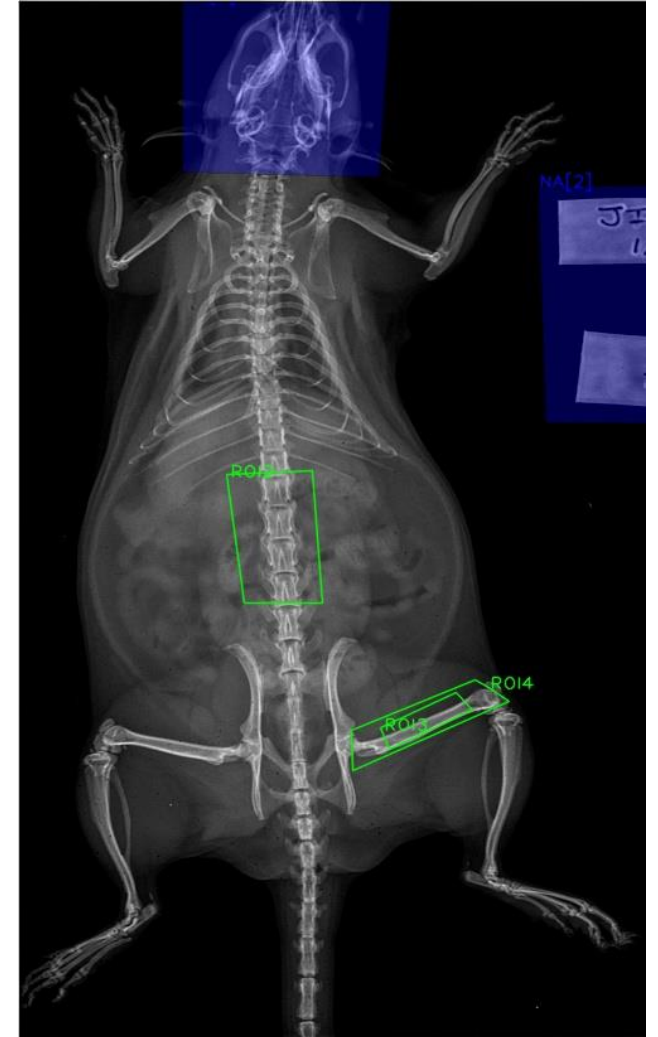
## Rat Model of Osteoporosis:

- Well established model, highly predictive of human efficacy
- Ovariectomized (OVX) female rats display bone loss similar to postmenopausal human females
- OVX female rats also respond to PTH analogs and other osteoanabolic agents similarly to humans

**Objective:** To evaluate the effect of daily RT-102 drug substance intraperitoneal injections on bone mineral density (BMD) in a rat model of osteoporosis.

## Key endpoint: Bone Mineral Density (BMD)

- determined using the same sensitive technique (DXA\*) used clinically in humans



\*Dual-Energy X-ray Absorptiometry

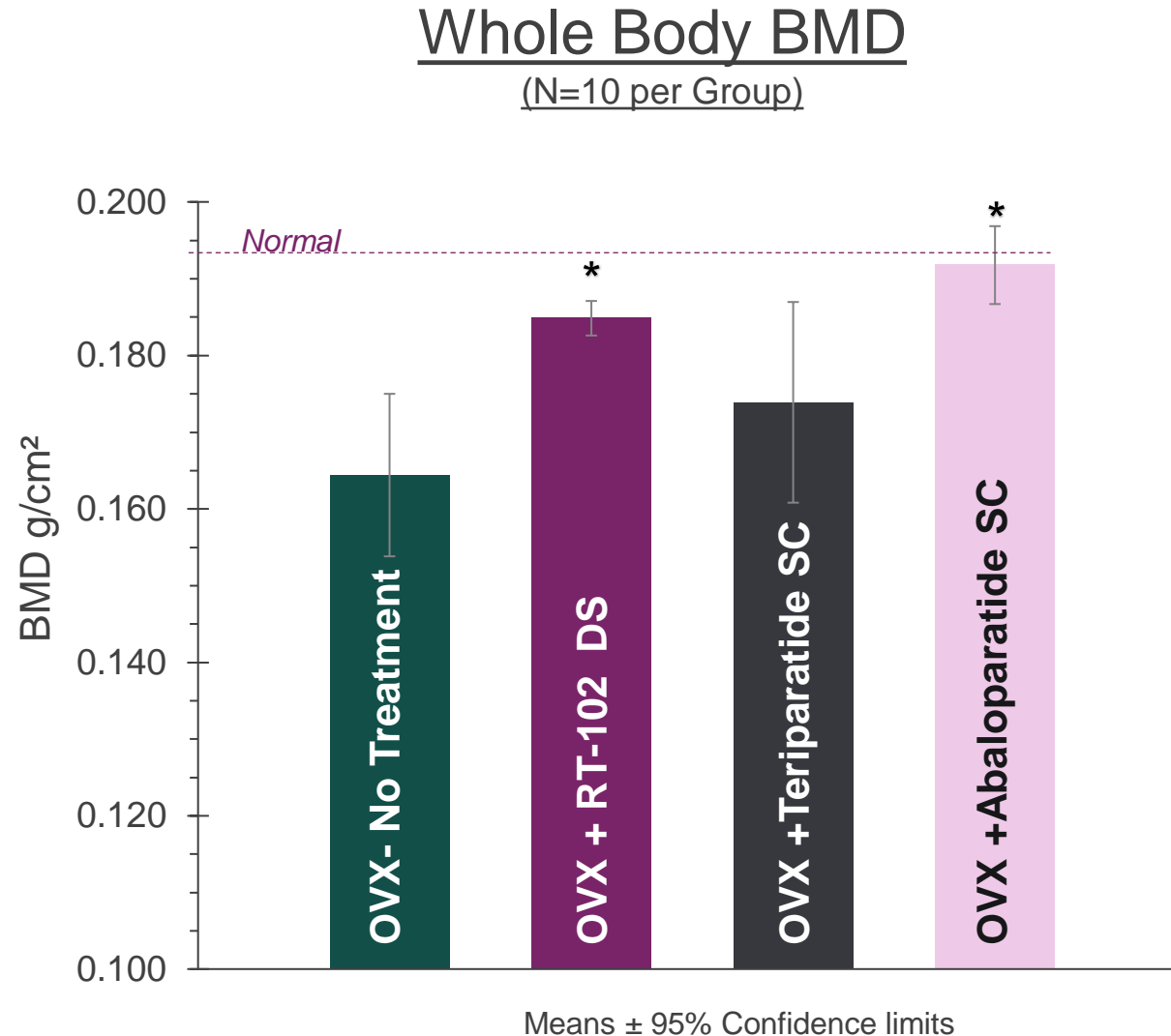
# Study Overview: A preclinical head-to-head comparison of RT-102 Drug Substance (DS) with Teriparatide (Forteo) and Abaloparatide (Tymlos)

Group/Treatment (N)	Dose level (µg/kg/day)	Human Equivalent Daily Dose
OVX-Vehicle Control (10)	0.0	n/a
OVX-RT-102, IP (10)	5.0	60µg
OVX-Teriparatide, SC (10)	5.0	60µg
OVX-Abaloparatide, SC (10)	5.0	60µg

**Key endpoint:** Bone mineral density (BMD) following 6 weeks of treatment with daily intraperitoneal (IP) injections

- The IP injection is designed to mimic the RaniPill route of delivery (Rani route).

# Results: Effects on Bone Mineral Density Following 6 Weeks of Treatment



\* = Significant,  $p < 0.05$  vs OVX group



# Rat PD Study Summary

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1. RT-102 DS increased BMD in a rat model of osteoporosis
2. RT-102 DS delivered via the Rani Route was biologically active comparable to SC injected PTH analogs

# RT-102 Program Summary

# RT-102 Studies\*: Key Take-aways



PK data from Phase I study showed robust and reproducible PK profiles of PTH delivered via the RaniPill



Bioavailability of PTH delivered by RaniPill was greater than that of SC injection



PD data from rat study demonstrated that RT-102 drug substance was biologically active



The PK data combined with PD data from the rat study suggest that RT-102 has the potential to deliver PTH at levels required for osteoporosis treatment

# RaniPill Platform Opportunity

# RaniPill Capsule Development Pipeline

	INDICATION(S)	FORMULATION	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT EXPECTED MILESTONE
CORE PROGRAMS							
RT-101	NETs / Acromegaly*	Octreotide					Repeat Dose Platform Study in 2022
RT-102	Osteoporosis	PTH-OP					Complete Phase 1 Part 2 repeat dose study
RT-105	Psoriatic Arthritis	Anti TNF- $\alpha$ Antibody					Initiate Phase 1 in 2023***
RT-109**	GH Deficiency	hGH					Initiate Phase 1 in 2022***
RT-110	Hypo-parathyroidism	PTH-Hypo					Initiate Phase 1 in 2023***
COLLABORATION OPPORTUNITIES							
RT-103	T2 Diabetes	GLP-1 Mimetic					
RT-106	T2 Diabetes	Basal Insulin					

RT-XXX refers to the RaniPill capsule containing a biologic or drug in a proprietary Rani formulation

\* Each of these indications will require separate trials









\*\* CCHN will have limited opportunity to negotiate for rights within China

\*\*\*Timelines are subject to regulatory agency review and feedback, which may result in delays

# The RaniPill is a Platform Technology with 90+ Eligible Drug Candidates

PLATFORM DEVICE	CAPACITY	POTENTIAL # OF DRUGS ENABLED	SELECT POTENTIAL DRUGS
<b>RaniPill GO (original)</b>	Up to 3 mg	>40	<ul style="list-style-type: none"><li>• Octreotide</li><li>• Parathyroid hormone for osteoporosis</li><li>• Parathyroid hormone for hypo</li><li>• Anti TNF-<math>\alpha</math> antibody</li></ul>
<b>RaniPill HC* (High-Capacity)</b>	Up to 20 mg	>50	<ul style="list-style-type: none"><li>• Pembrolizumab / Keytruda®</li><li>• Dupilumab / Dupixent®</li><li>• Trastuzumab / Herceptin®</li><li>• Secukinumab / Cosentyx®</li></ul>

# Patients Prefer Pills

								
Injection Frequency	Daily	Every 2 weeks	Every month	Every month	Every month	Every 2 months	Every 3 months	Every 6 months
% Prefer to Take Daily Pill Over Current Injectable Regimen	87%	88%	74%	73%	75%	77%	64%	76%

\*Data for Entyvio, Simponi, Evenity, Cosentyx, Stelara, and Prolia obtained from an independent third-party survey commissioned by Rani in the second quarter of 2021 to investigate U.S. patient preference for a daily oral drug alternative versus injections. Patients surveyed (n=611) were aged 18 years or older and presently used an injectable biologic to treat a condition. Six patient groups each included 100-103 patients with current primary treatment being injections of Simponi, Entyvio, Stelara, Prolia, Evenity, or Cosentyx.

\*Data for Lantus and Humira obtained from an independent third-party survey commissioned by Rani in 2017 to investigate U.S. patient preference for a daily oral alternative. 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.

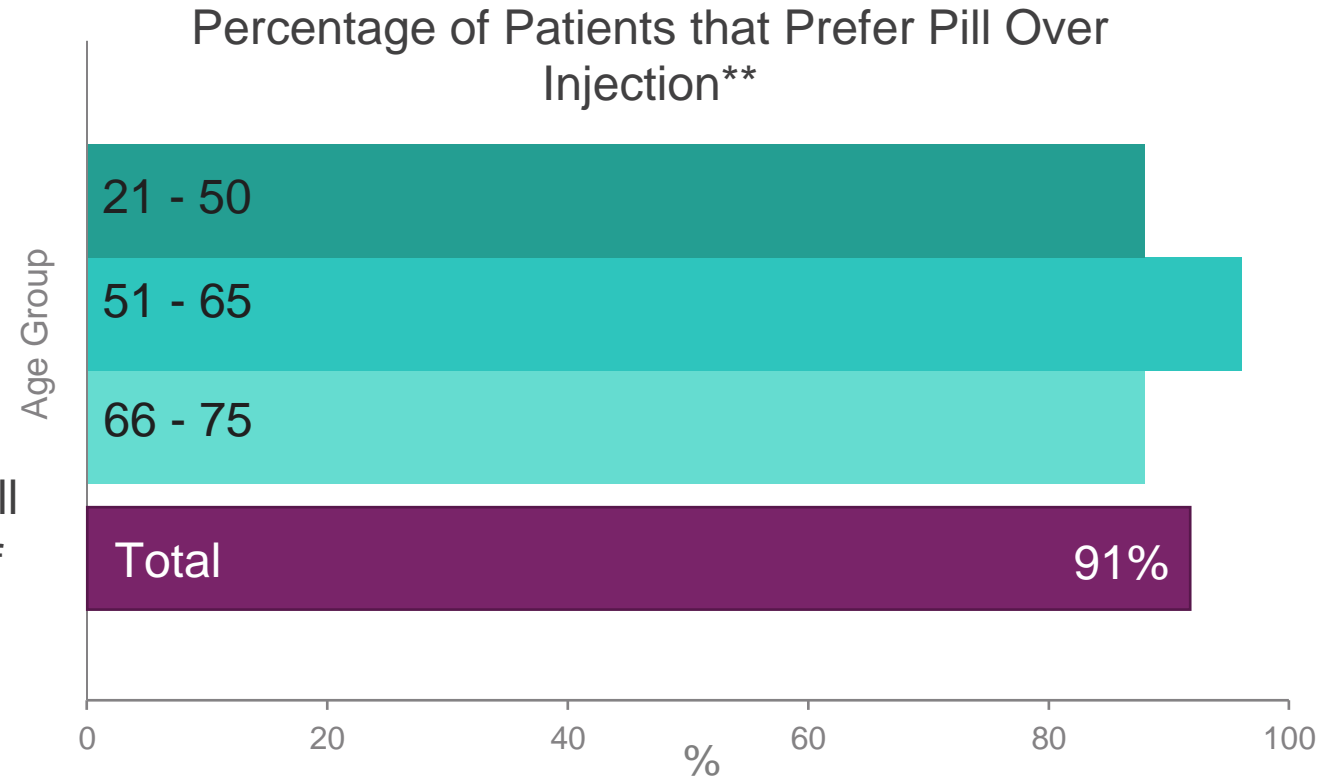
# Mock-RaniPill\* Swallow Study Overview

## Study Objective

To evaluate the ease of swallowability of a mock-RaniPill by patients of different ages (N=50 per arm)

## Key End Points

- Swallowability and palatability of the mock-RaniPill
- Participants' preference to choose a pill instead of their current injection therapy

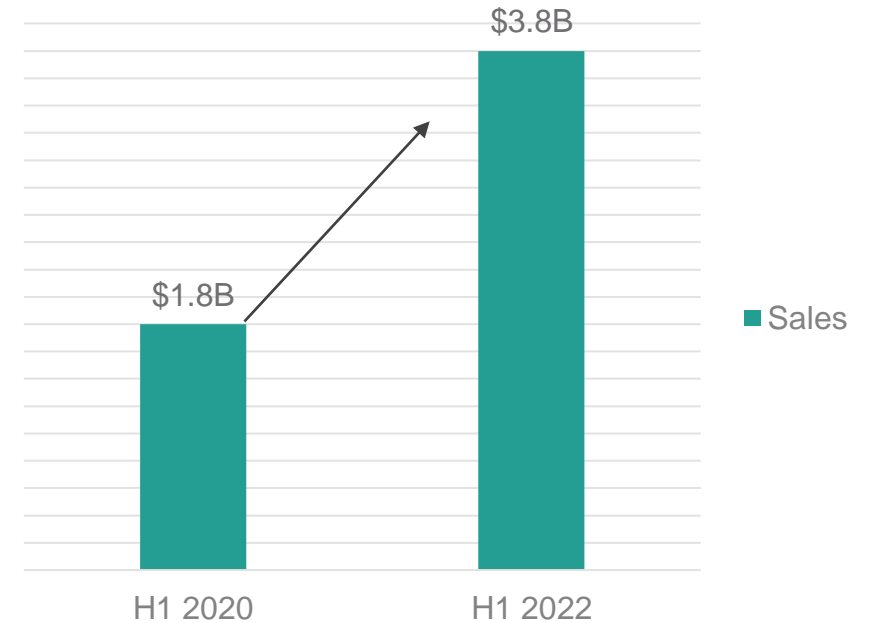


- ❖ 100% of patients successfully swallowed mock-RaniPill
- ❖ 84% indicated pill was easy or somewhat easy to swallow



# Patient Preference Drives Sales & Growth

85% of J&J's IV Darzalex converted to subcutaneous formulation

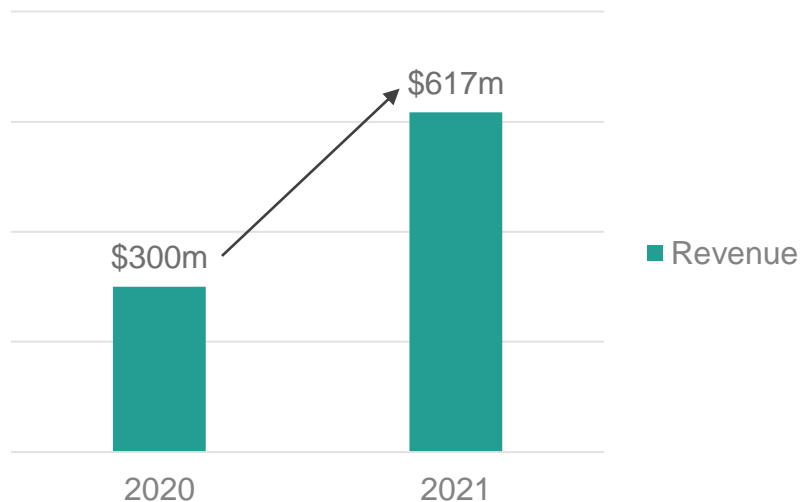


Introduction of subcutaneous administration increased Darzalex sales by 111%

# Examples of Oral Therapies as Growth Drivers

## Novo Nordisk's oral semaglutide for diabetes

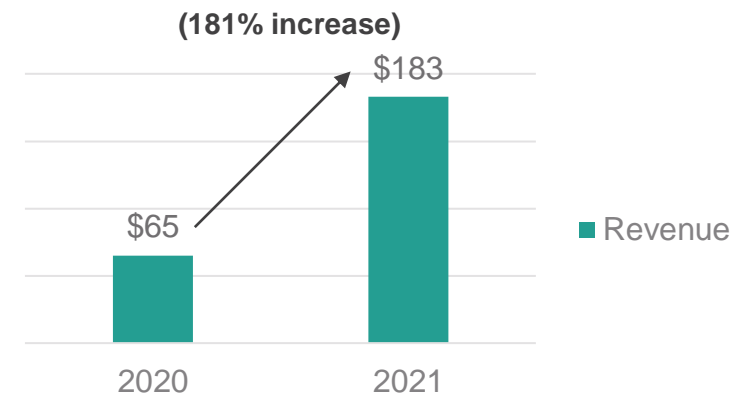
- Launched in Q4 2019



## Oral CGRP vs. Injectable CGRP for migraine

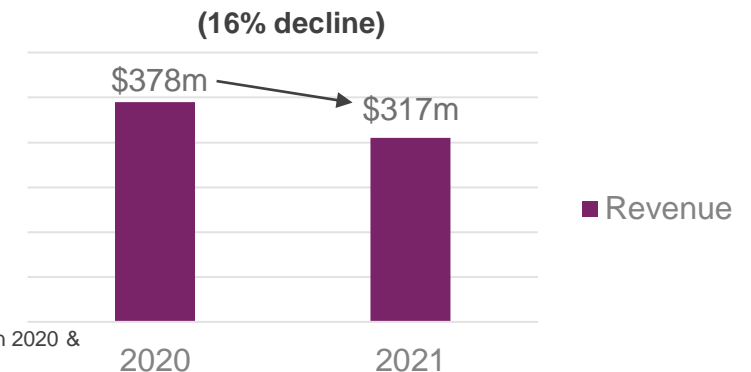
### Allergan's Ubrelvy® (oral CGRP)

- Launched in 2020



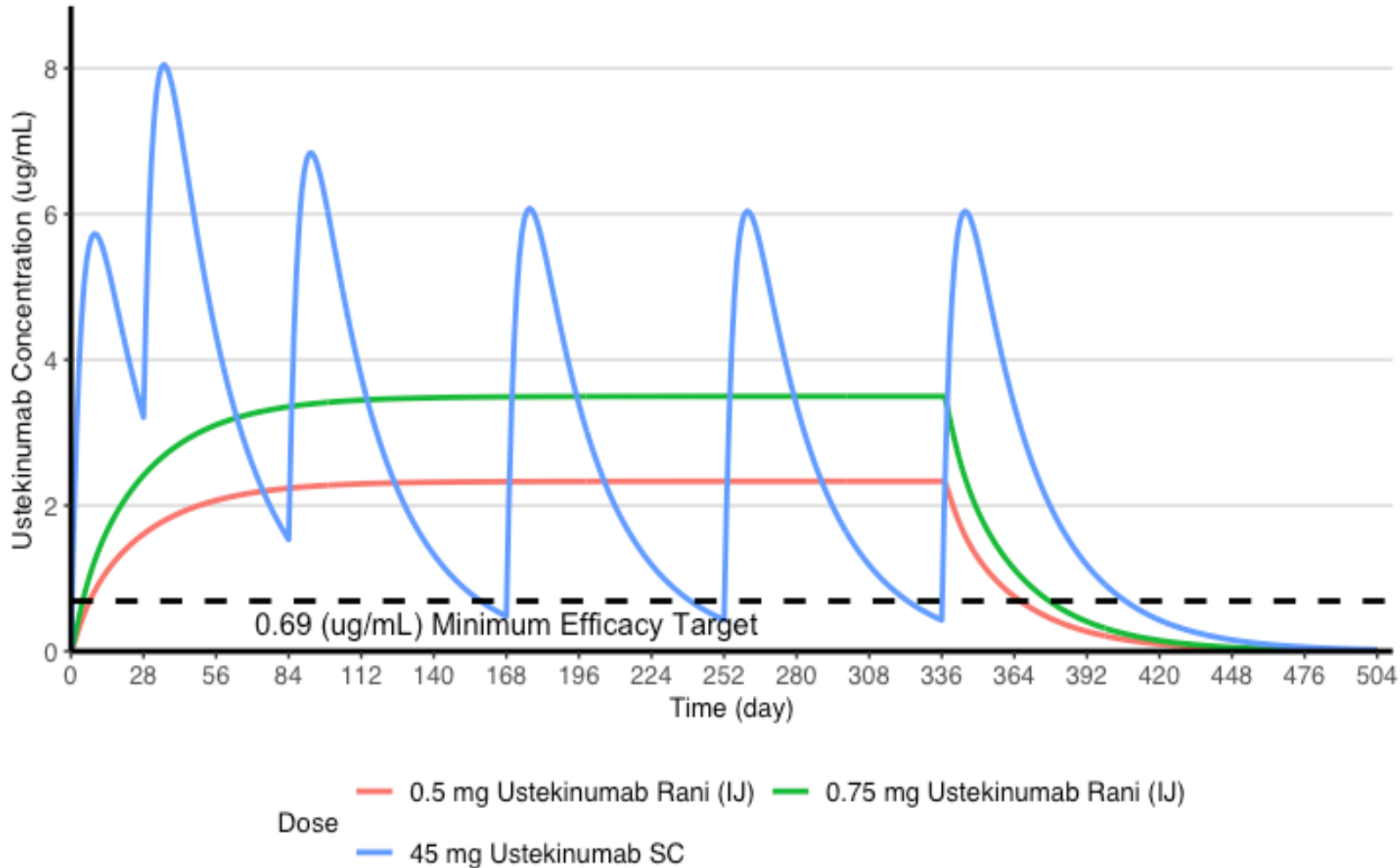
### Amgen's Aimovig® (injectable CGRP)

- Launched in 2018



# The Potential Power of Daily Dosing

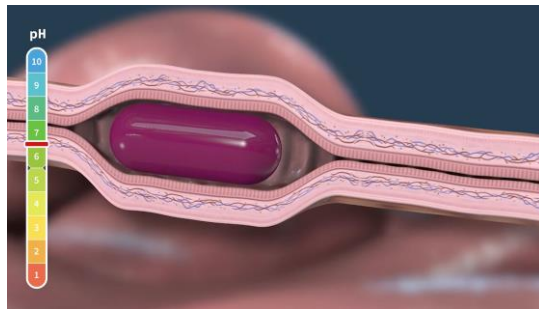
Steady State PK simulations of Ustekinumab  
(45 mg SC quarterly vs. Rani 0.5 and 0.75 mg oral daily)



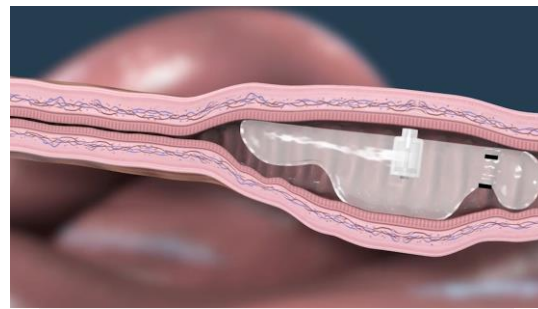
# RaniPill Technology Overview

# Rani's Technology

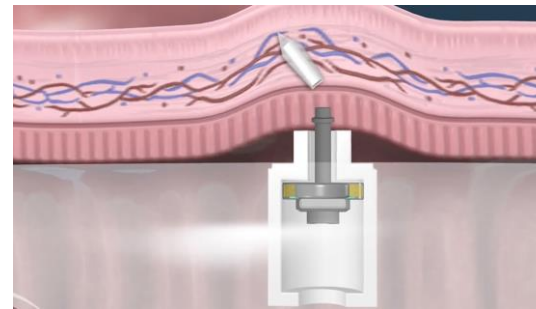
## *Cross Section of Intestinal Wall Illustrating Deployment of the RaniPill Capsule*



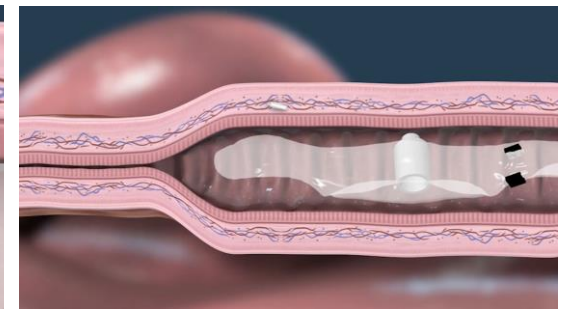
A: RaniPill capsule with protective coating in intestine.



B: Outer shell dissolves and the balloon starts to inflate as the reaction begins.



C: Pressure in the balloon pushes the microneedle into the intestinal wall.



D: Balloon deflates and passes on.

# Rani's Development Approach

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- **Designed for minimal discomfort**  
No small intestine pain receptors
- **Designed for absorption similar to injections**  
Upon deployment
- **Agnostic to payload**  
Designed to accommodate peptides, proteins and antibodies
- **Strong patent position**  
Covering both the platform and drugs in combination with the platform
- **Scalable design**  
Designed to achieve low cost, high volume manufacturing



*The RaniPill capsule is similar in size to a fish oil or calcium pill*

# Our Goal is to Become *The* First-Line Biologics Company

INDICATION	STARTING THERAPIES		<div><div>Rani</div><div>THERAPEUTICS</div></div> <div>Oral RaniPill® Biologics</div> <div></div>	STANDARD INJECTABLES	
Type 2 Diabetes	Metformin (oral)	DPP-4 (oral)		Basal Insulin & GLP-1 (injections)	
Osteoporosis	Bisphosphonates (oral)			Teriparatide (injection)	Denosumab (injection)
Hypoparathyroidism	Calcitrol (oral)			PTH(1-84) (injection)	
Rheumatoid Arthritis	Methotrexate (oral)	JAK inhibitors (oral)		TNF-α (injection)	
High Cholesterol	Statins (oral)			PCSK-9 Inhibitors (injection)	
Crohn's Disease	Steroids & 5-aminosalicylates (oral)			TNF-α, α4-Integrin (injection)	IL-12/23 (injection)
Psoriasis / Psoriatic Arthritis	JAK inhibitors (oral)			IL-17 (injection)	TNF-α (injection)

Thank you



**Rani**<sup>®</sup>  
THERAPEUTICS