



*Our mission at Rani is to end  
painful injections for the  
millions of patients suffering  
from chronic diseases.*

Rani Therapeutics  
Corporate Presentation

December 2023

# 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, 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, the ability of our restructuring announced in November 2023 to deliver the expected results, 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, 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 and our Quarterly Reports on Form 10-Q, and our other public filings made with the SEC and available at [www.sec.gov](http://www.sec.gov).

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



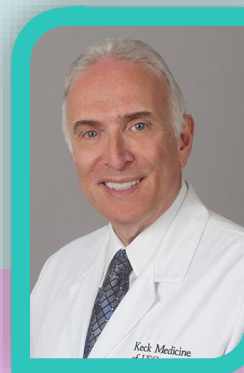
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# Rani Is Pioneering Oral Biologics with Potential Best In Class Technology

## 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

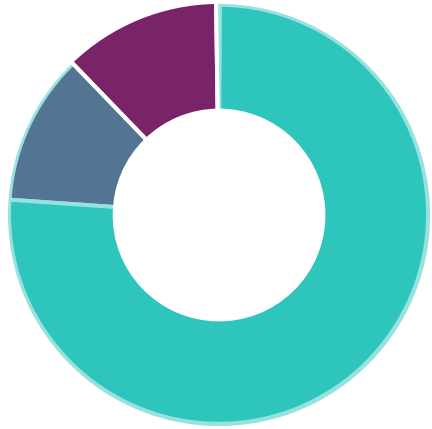
## Ahead of Other Oral Devices

- 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** <sup>[1]</sup>

**88% of patients** with injection regimen of **every 2 weeks** <sup>[2]</sup>

Inconvenience impacts treatment adherence



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

Therapies could start earlier with an oral alternative



**81% of endocrinologists** would initiate basal insulin therapy earlier with an oral option <sup>[3]</sup>

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



# Rani's Approach:

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

Best Therapeutic + Best Delivery

Opportunity

Strategy

Value

- 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

- **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

# Partnered with Celltrion On Two Important Assets

## Ustekinumab Biosimilar (RT-111)

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

## Adalimumab Biosimilar (RT-105)

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



- 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

# Development Pipeline

	INDICATION(S)	FORMULATION	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT EXPECTED MILESTONE*
CORE PROGRAMS							
RT-102	Osteoporosis	PTH-OP					Initiate Phase 2 in 2024
RT-111	Psoriasis	Ustekinumab**					Phase 1 ongoing; topline data expected early Q1 2024
RT-105	Psoriatic Arthritis	Adalimumab**					Initiate Phase 1
RT-110	Hypo-parathyroidism	PTH-Hypo					Initiate Phase 1

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 a Phase 1 study



# Robust Database to Support Our Technology

## Preclinical

### 15 Molecules Assessed

antibodies, peptides, and large proteins

### >6800 Capsules

tested *in vitro* & *in vivo*

### 60-Day GLP Study

completed

## Clinical

### 3 Phase I Studies

2 completed, 1 ongoing

### 193 RaniPill Capsules

administered in 106 humans\*

### 7-Day Repeat Dose Study

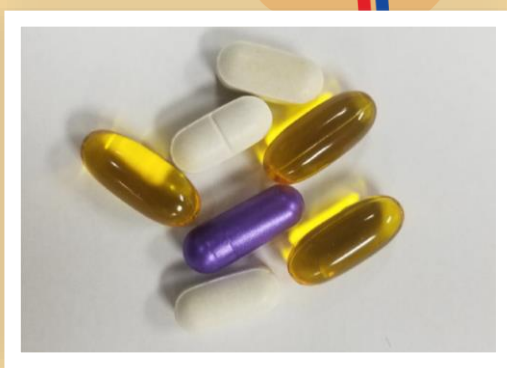
completed



Established IP portfolio with 425+ patent applications filed and 225+ patents granted

\* As of 8/1/23

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

# Rani Platform has Clinically Demonstrated Tolerability and Favorable Safety Profile

In two completed Phase 1 studies:

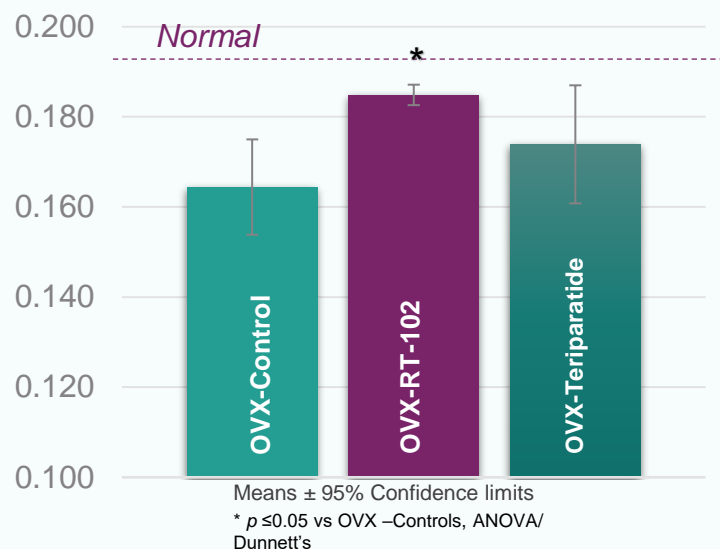
- ✓ RaniPill was well-tolerated
- ✓ No serious adverse events

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%)

# Demonstrated Biologic Activity in Preclinical Pharmacodynamic Studies

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

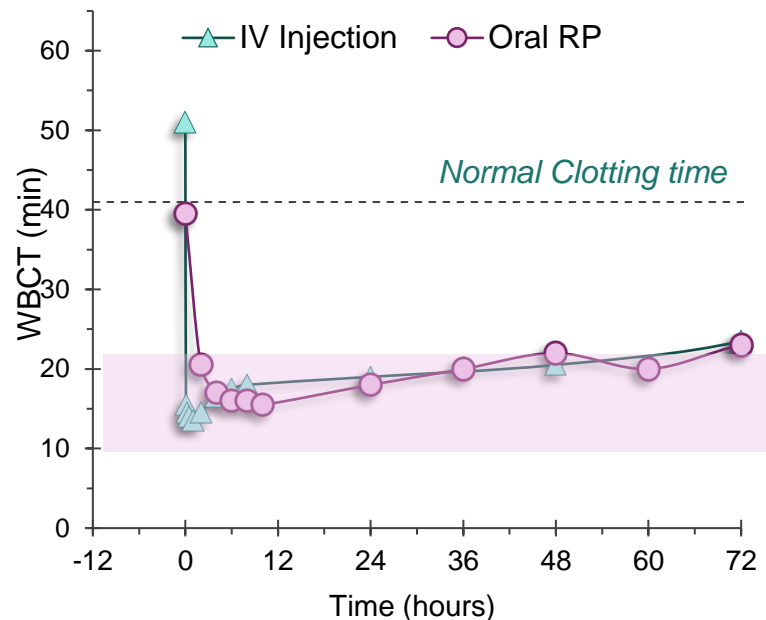
Osteoanabolic Effect of RT-102 Drug Substance on Whole Body Bone Mineral Density (BMD)



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

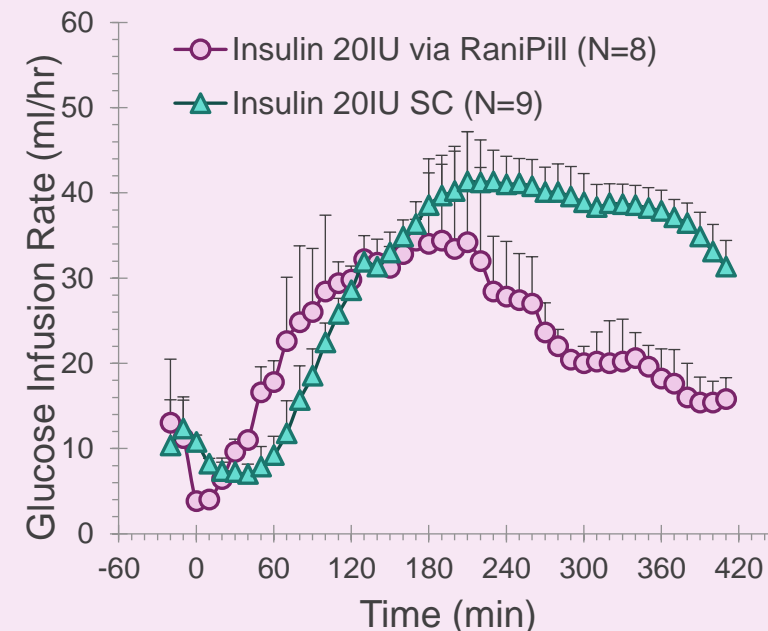
## Factor VIII (RT-108) Normalized Coagulopathy in A Canine Model of Hemophilia A



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

# Safety and Tolerability of RaniPill Drug Delivery Platform Following 60 Consecutive Days of Daily Administration in Preclinical GLP Study

## Study Overview

Naïve Beagle dogs (N=36) were administered:

- **RaniPill:** RT-100 (RaniPill containing Mannitol-filled needle (N=24))
  - Subgroup (N=12) was tracked for additional 14 days post completion of study
- **Mock-RP:** Control (capsule filled with potato starch (N=12))

## Key Safety Checks:

- ✓ Weekly radiographs to ascertain safe passage/excretion of device remnants
- ✓ All subjects underwent comprehensive gross and histopathologic examinations with emphasis on GI tissue to assess safety of the RaniPill

- The RaniPill was well-tolerated with no treatment-related adverse events
- All animals remained clinically healthy throughout the study

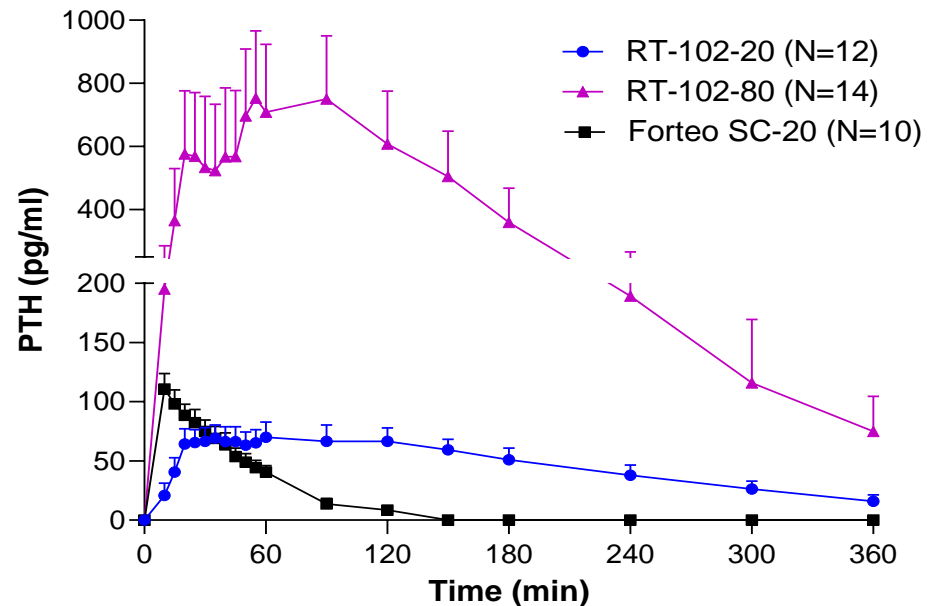
# Pipeline Programs





# RT-102: Positive Phase I Data for Osteoporosis

PK Profiles of Single Doses of RT-102



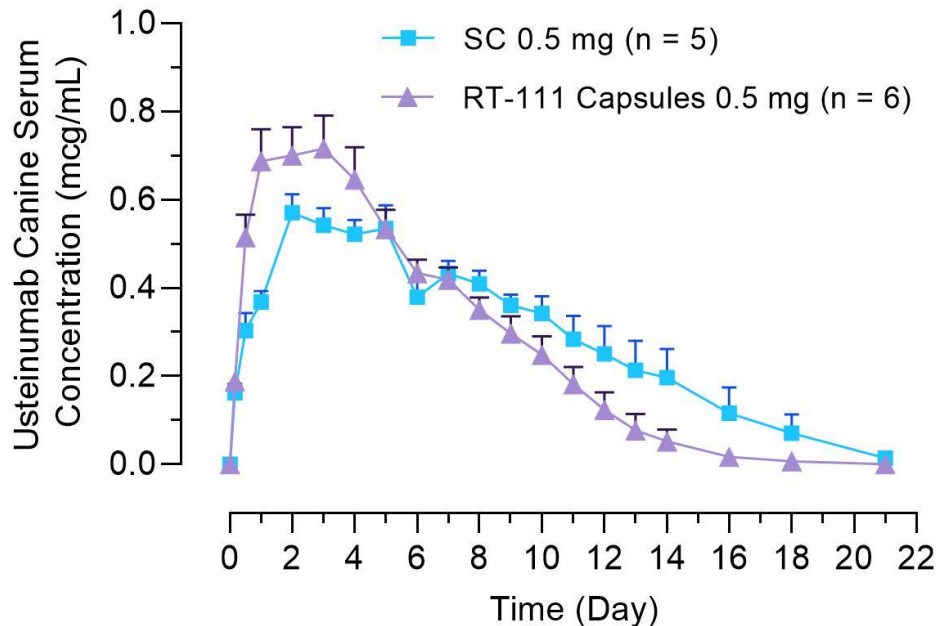
## Safety & Tolerability:

- ✓ 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 2024

# RT-111: Oral Ustekinumab Development



**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)

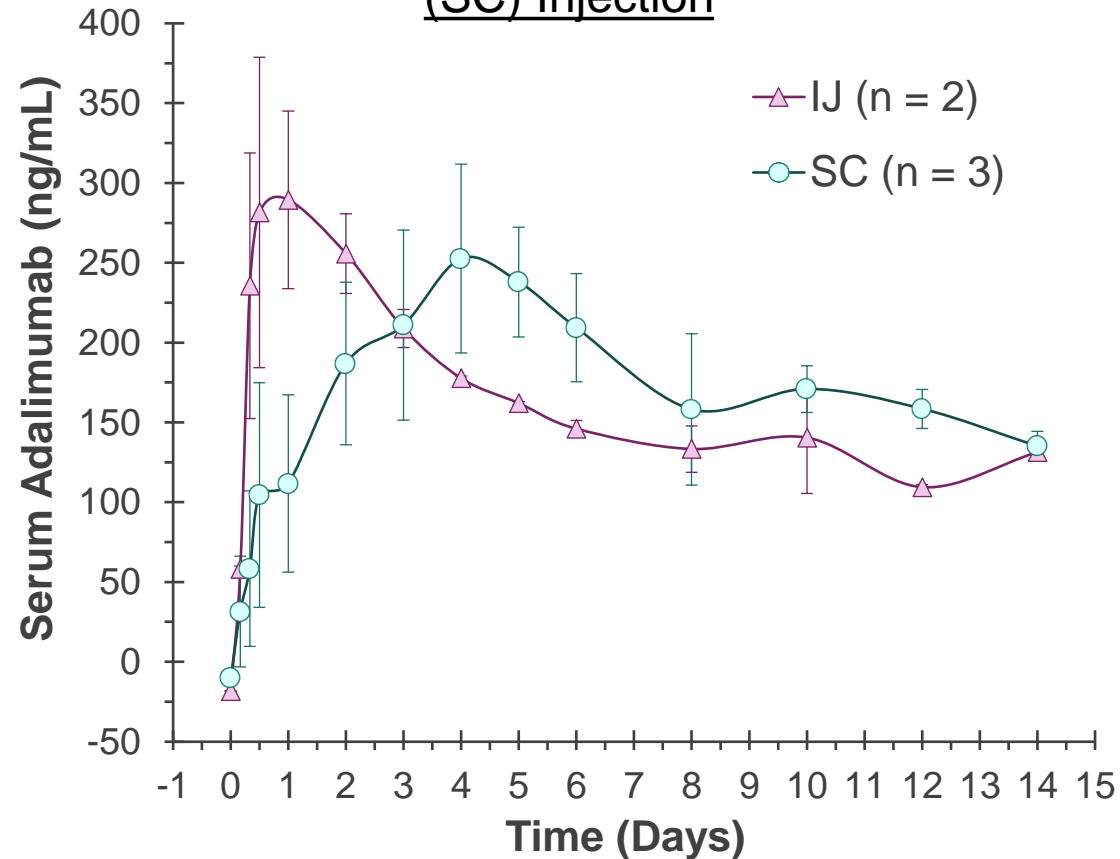
## Anticipated Next Steps:

- Phase I trial ongoing, topline data expected in Q1 2024
  - Single dose, healthy volunteers
  - Testing doses of 0.5 and .75 mg

Route	Pharmacokinetic Parameters (Mean ± SEM)		
	C <sub>max</sub> (µg/mL)	T <sub>max</sub> (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-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

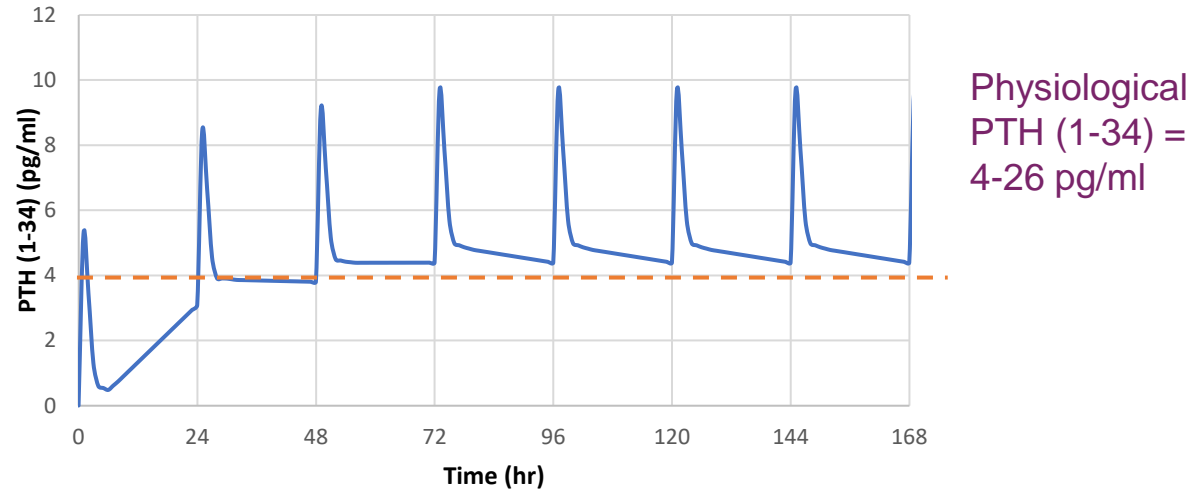
**Adalimumab Delivered via the RaniPill Route  
of Administration Demonstrated PK  
Comparable to SC Injection**

## 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



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:

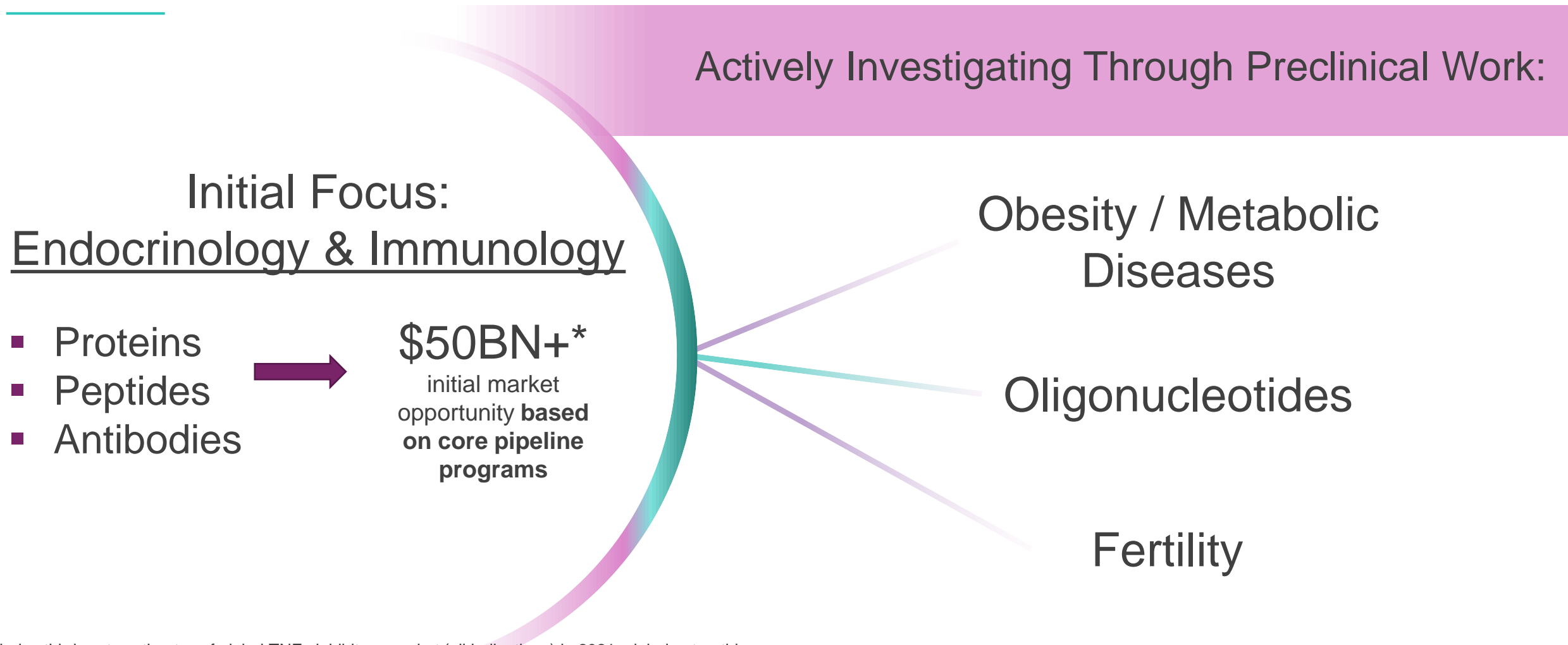
- Significant unmet medical need
- Conventional therapy aimed at short-term symptom management with large doses of oral calcium and active vitamin D as first-line therapy option
- Market forecast to reach \$2.64B by 2030 <sup>[7]</sup>
- All other long-acting PTH formulations currently under development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

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

# Discovery Programs



# Strategic Focus Areas



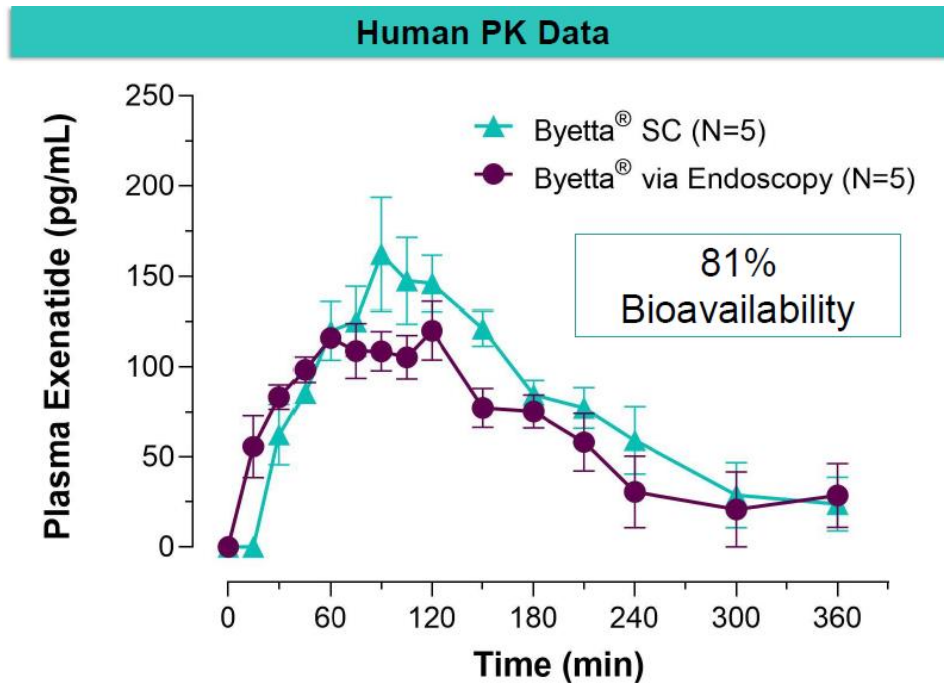
\* Includes third-party estimates of global TNFa inhibitors market (all indications) in 2021, global octreotide market in 2022, global parathyroid hormone market in 2022, and reported global sales of Stelara in 2022.

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



# 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:

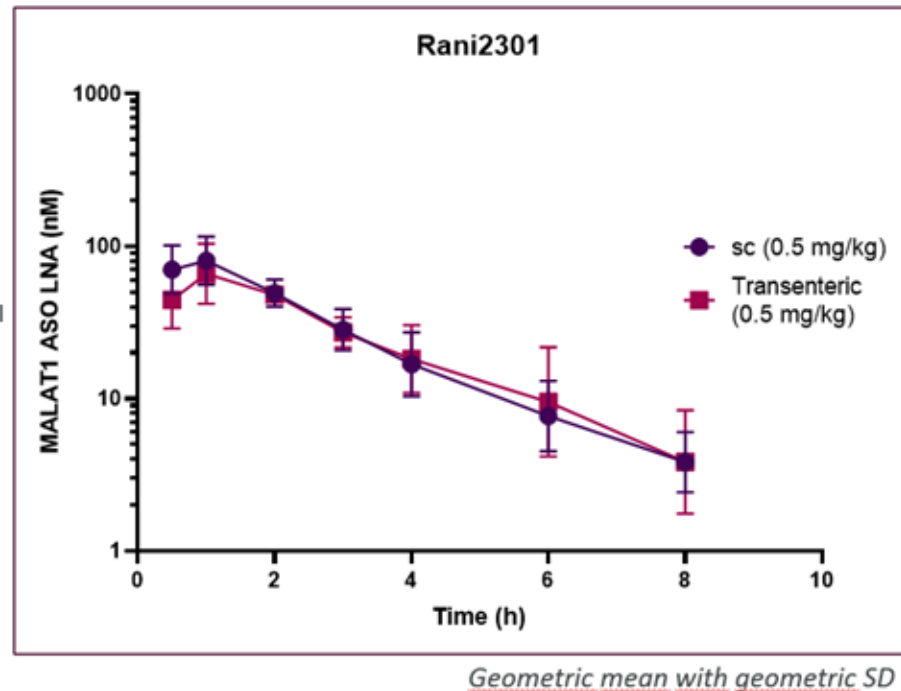
- Large and growing patient population seeking treatment options for obesity
- Approved therapies for obesity are non-ideal
  - Majority of obesity treatments are monthly or weekly injectables
  - Low bioavailability leading some to explore extremely high dosing (up to 145x SC dose <sup>[8]</sup>)
  - 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

# 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:

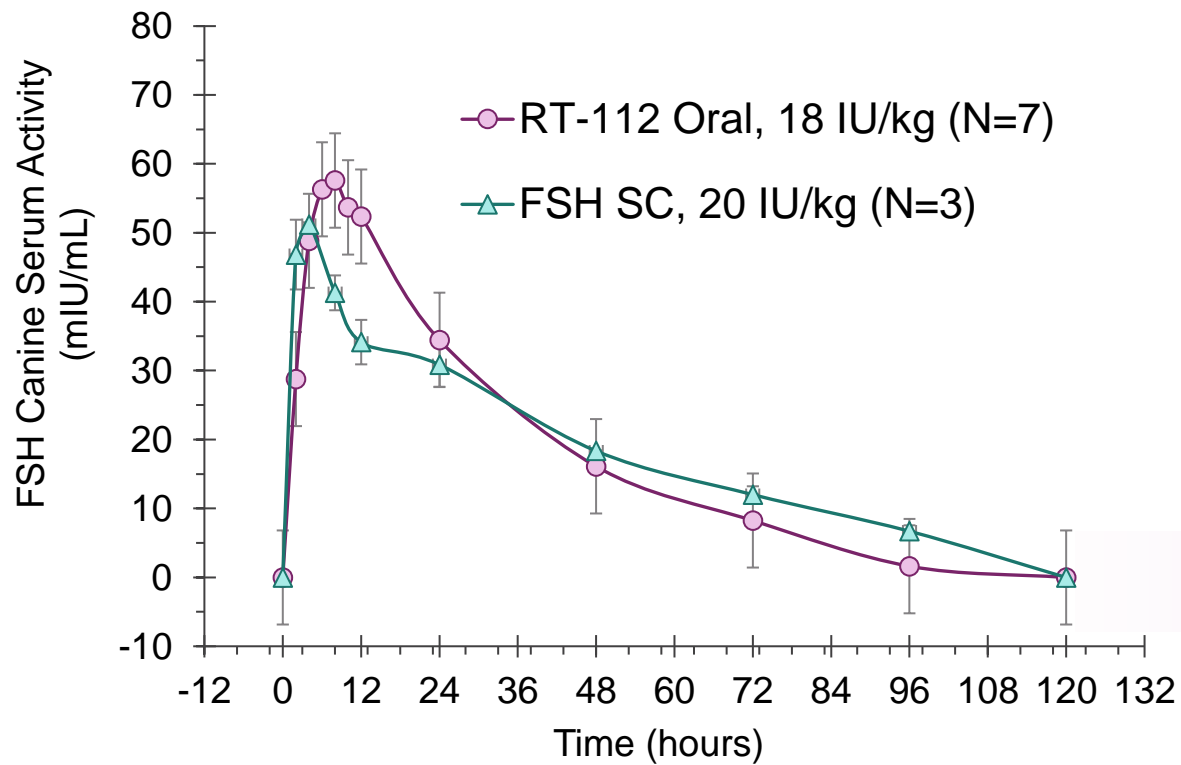
- Emerging area of drug development that offers a promising alternative to therapies targeting downstream processes
- Chemistry attempts at oral delivery have had mixed results in terms of bioavailability

## 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.<sup>[9]</sup> 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 <sup>[10]</sup>
  - Between 2009 and 2016, number of women in the US who froze their eggs rose by more than 1,000% <sup>[11]</sup>
- Cash pay for high-cost treatment
- 7–14-day treatment
- Burdensome and difficult to administer injections

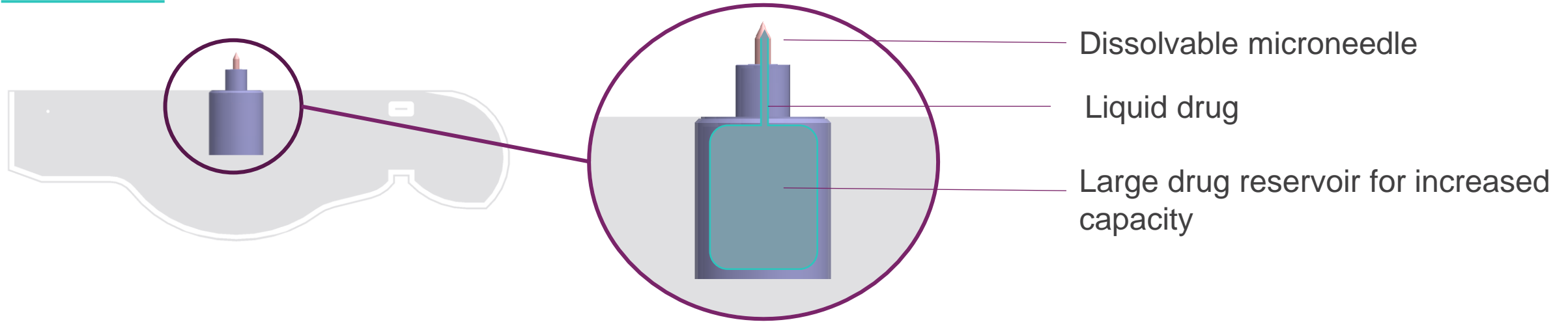
## Rani Strategy:

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

# RaniPill HC 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)  
Dupixent (dupilumab)

Herceptin (trastuzumab)  
Enbrel (etanercept)

Cosentyx (secukinumab)

## Transenteric Delivery of Liquid Drug

- Minimizes formulation steps required

## Leverages Common Components and Manufacturing Processes from RaniPill GO

# Progress Demonstrating the RaniPill HC Capabilities

## Tested multiple drugs including proteins and monoclonal antibodies

- Fe57 (iron)
- PTH 1-34
- Humira® (adalimumab)
- Anti-interleukin antibody



Tests demonstrated success rate comparable to RaniPill GO (device used in all clinical trials to date)



Successfully delivered 16+ mg of drug which significantly increases potential RaniPill candidates

## Next Steps:

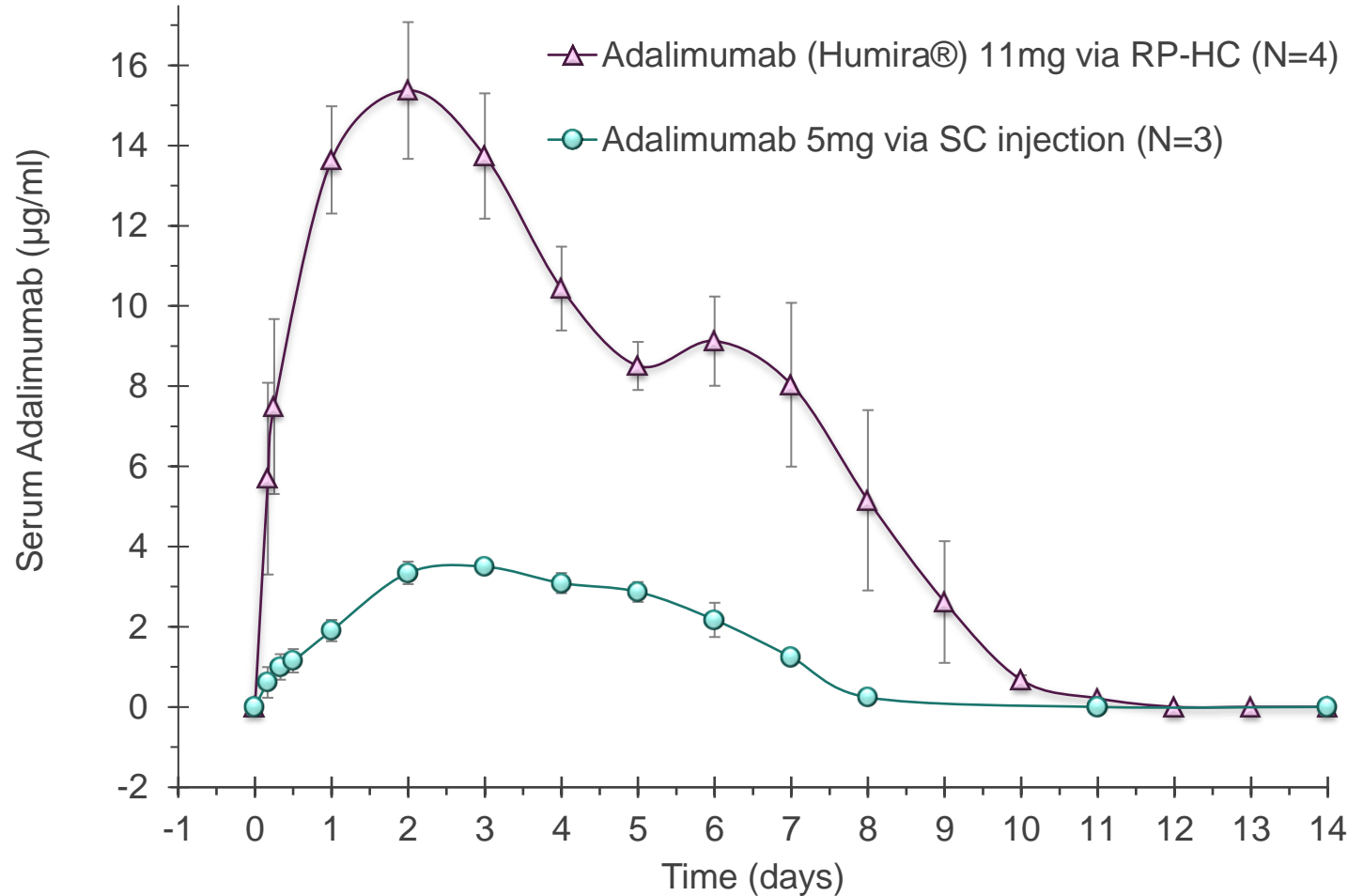
- Actively increasing capacity with goal of enabling 30mg\* total capacity and improving success rate
- Expect to enter the clinic in 2024



Preliminary preclinical testing supports the potential for RaniPill HC to deliver high bioavailability



# Adalimumab 11mg via RaniPill HC vs 5mg via Subcutaneous Injection\*



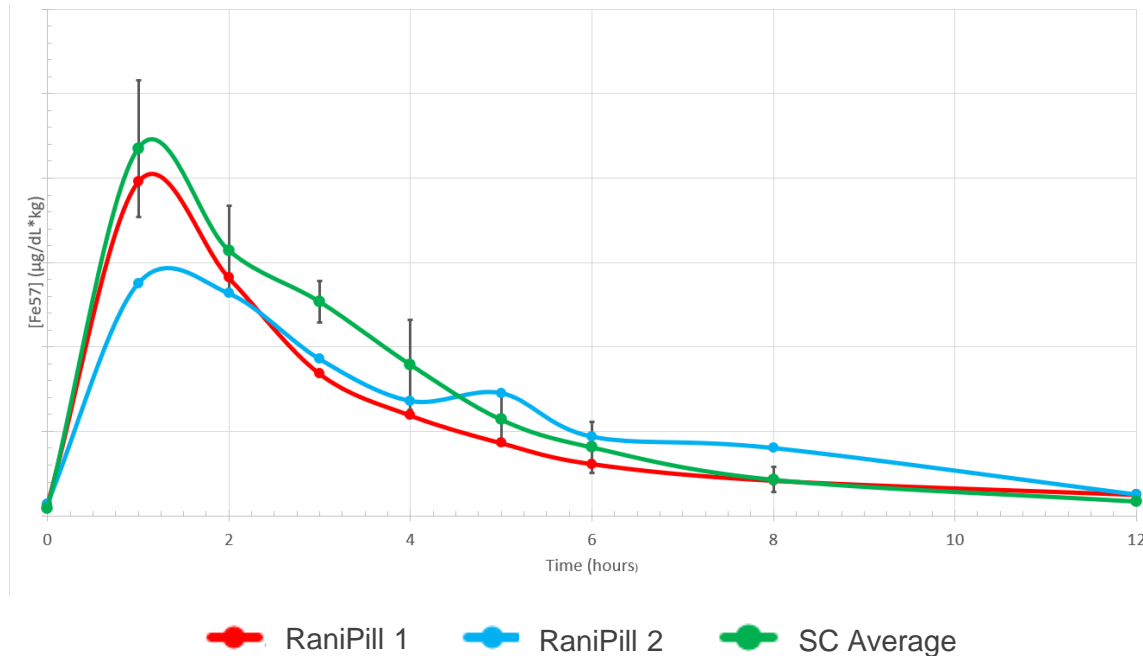
Data are Means  $\pm$  SE

- All 4 RaniPills successfully delivered payload
- 11mg dose was well-tolerated, with no clinical findings throughout the study
- Remnants excreted normally without sequelae

*\*Historical SC injection data with an adalimumab biosimilar (GP2017)*

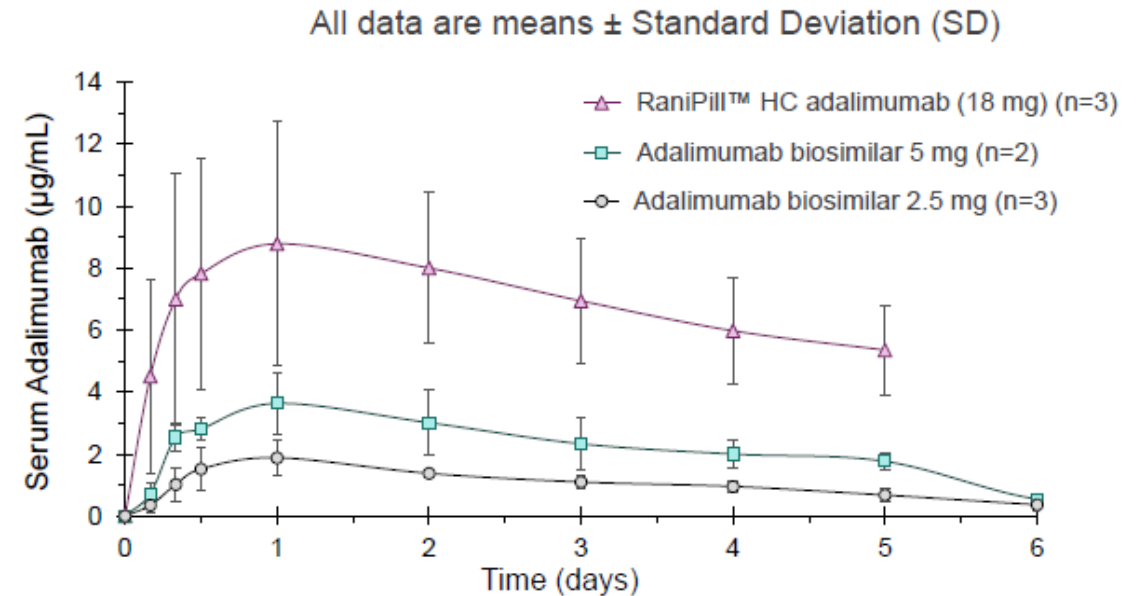
# RaniPill HC Shows Drug Signal Comparable to SC Injection\*

## 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 Adalimumab Biosimilar in Awake Canines



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

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

Initial Analysis of Drug Delivery Via the RaniPill HC Shows Potential for Mimicking Parenteral (Subcutaneous) Administration

# Anticipated Upcoming Milestones & Progress

- Initiate a Phase 2 clinical trial with RT-102 in 2024
- Topline Data from Phase 1 clinical trial with RT-111 in Q1 2024
- 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

A close-up photograph of a person's open palm holding a single, small, purple, oval-shaped pill. The background is a soft-focus image of a person's face, which is overlaid with a semi-transparent purple filter. The text 'Thank You' is written in white, sans-serif font across the middle of the hand.

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 <sup>[12]</sup>

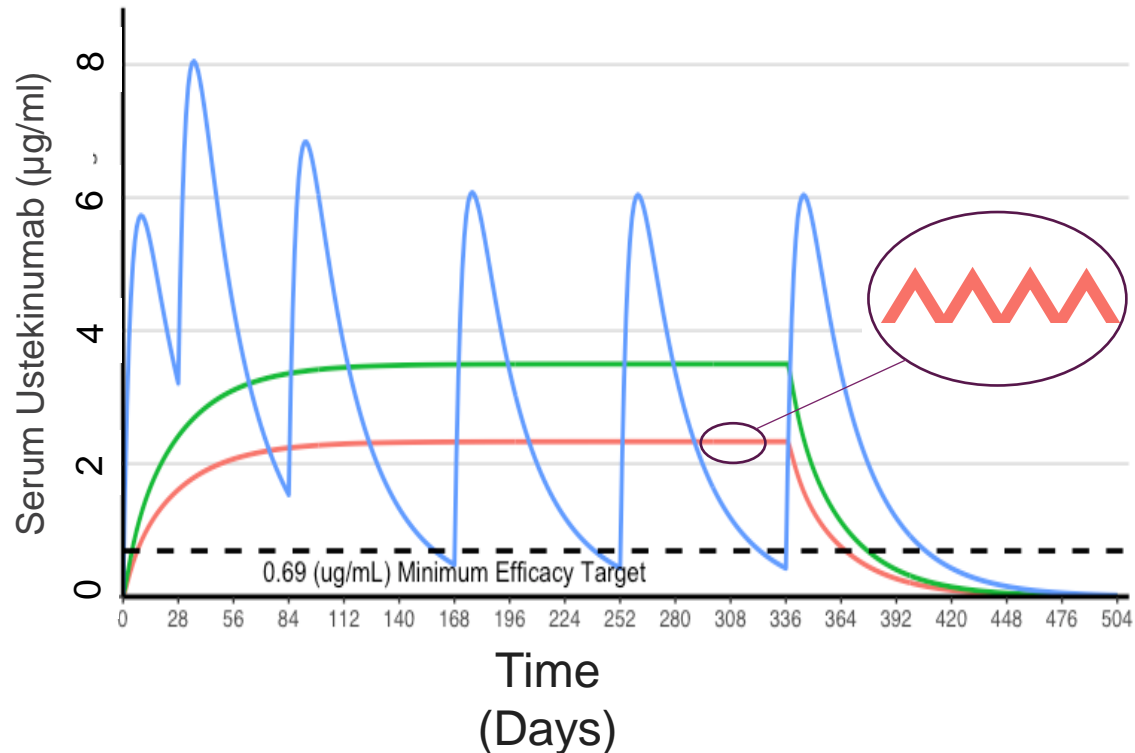
- Oral option addresses injection aversion
- Potential to grow market with earlier intervention with an oral option

Global PTH market expected to grow to \$2.51B in 2026 at CAGR of 4% <sup>[13]</sup>

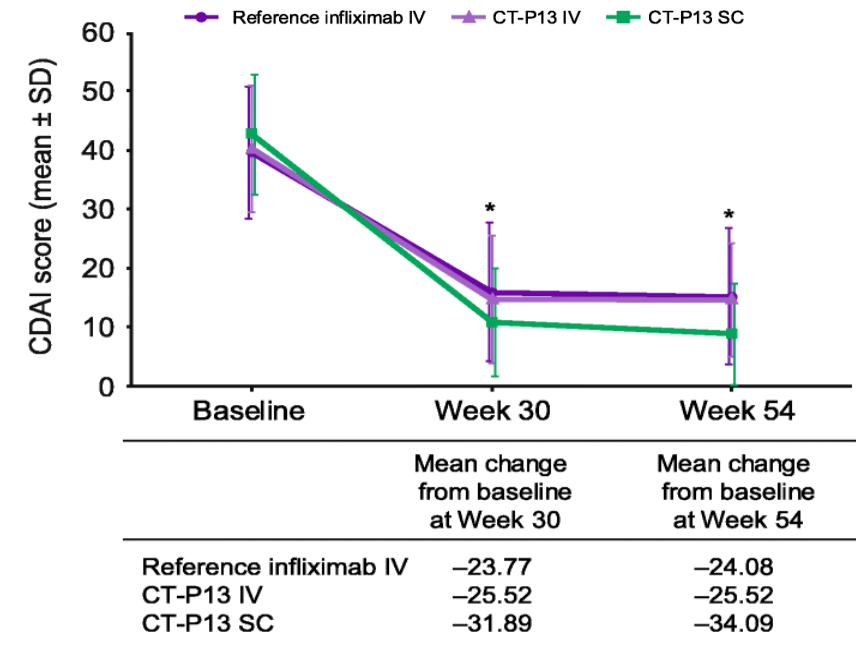
- Forteo (teriparatide) earned \$613M in revenue in 2022 <sup>[14]</sup>

# 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]



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	
	
Bank of America	Stifel
Cantor Fitzgerald & Co.	Canaccord Genuity
BTIG	

AUGUST 2022 – ATM Controlled Equity <sup>SM</sup> Sales Agreement
\$Up to \$150 million [not utilized to date]

Cantor Fitzgerald & Co.
H.C. Wainwright & Co., LLC

AUGUST 2022 - LOAN
Aggregate principal amount up to \$45.0 million; \$30M drawn to date

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] [reserved]
- [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.
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