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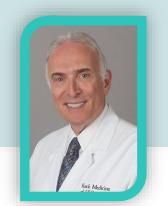
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Rani Therapeutics is a public, clinical-stage biotech company developing a platform technology for the oral delivery of biologic drugs.





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

Rani Therapeutics NASDAQ: RANI

Clinical-stage biotech focused on Oral Delivery of Biologic Drugs with Bioavailability Comparable to Parenteral Products

TECHNOLOGY:

RaniPill

- 200 μL Capacity (20-40mgs*)
- Liquid Drug Formulation

PIPELINE:

Programs across a variety of high value indications, including obesity, psoriasis, and osteoporosis

DISCOVERY:

Broad applicability across Nanobodies, Hemophilia, Bispecific MABs, Fertility, Genetic Medicine

IP:

472 Granted Patents and Pending Applications, 262 Granted Patents**



^{*}Dependent on drug concentration

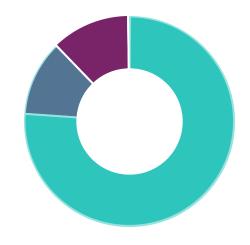
^{**} As of May 4, 2024

Substantial Unmet Need for Oral Administration of Biologics

Patients prefer daily pill over current injection regimen

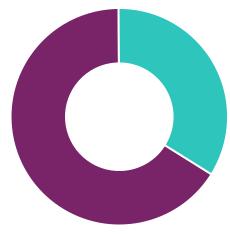
Inconvenience impacts treatment adherence

Therapies could start earlier with an oral alternative



76% of patients with injection regimen of every 6 months

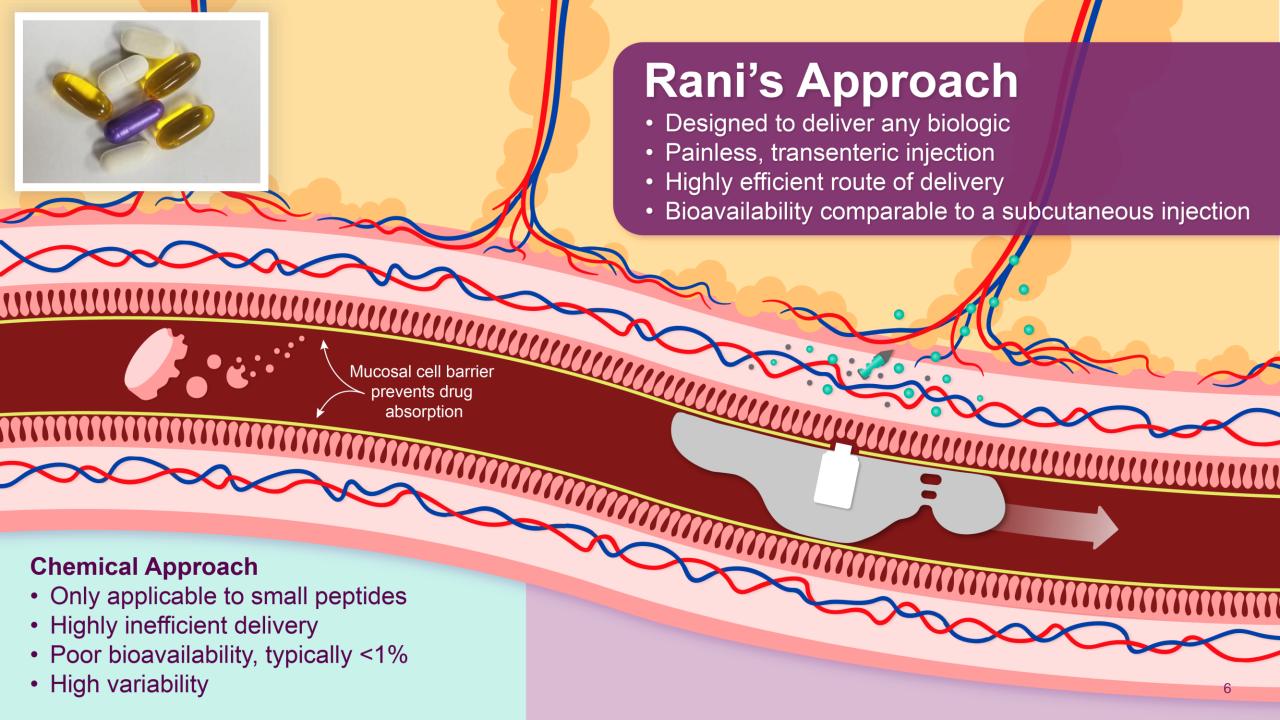
88% of patients with injection regimen of every 2 weeks



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



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



RaniPill Development Progress and Safety

Preclinical

15 Molecules Assessed

antibodies, peptides, and large proteins delivered with high bioavailability

>7000 Capsules

tested in vitro & in vivo

60-Day GLP Study

completed with no clinical findings

Clinical

3 Phase I Studies*

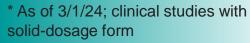
completed

233 RaniPill Capsules

administered to 146 humans

7-Day Repeat Dose Study

completed



Rani Platform has Demonstrated Tolerability and Favorable Safety Profile

60-Day Repeat Administration

in Awake Canines

- ✓ The RaniPill was well-tolerated.
- ✓ No treatment-related adverse events
- ✓ All animals remained clinically healthy throughout the study

3 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=131)				
Transient Abdominal Pain	2 (2%)				
Burping	1 (1%)				
Burning Sensation in Stomach	1 (1%)				



* Abdominal pain classified as mild. Burping lasted 2 days and was classified as moderate. Burning sensation in stomach perceived 1 hour after capsule administration and lasted for 30 minutes. However, drug levels were not seen for 10 hours after capsule administration indicating that the capsule had not deployed at time of the reported pain which suggests that this AE is not related to the drug or RaniPill deployment. However, presence of the undeployed capsule in the stomach could have causality to the reported pain and thus was included.

Development Pipeline

	INDICATION(S)	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT EXPECTED KEY MILESTONE*
CORE PROGR	RAMS					
RT-114	Obesity	GLP-1/GLP-2**				Initiate Phase 1 in 2025
RT-111	Psoriasis	Ustekinumab***				Advance Clinical Development at Higher Doses
RT-102	Osteoporosis	PTH-OP				Initiate Phase 2
RT-105	Psoriatic Arthritis	Adalimumab***				Initiate Phase 1
RT-110	Hypo-parathyroidism	РТН-Нуро				Initiate Phase 1



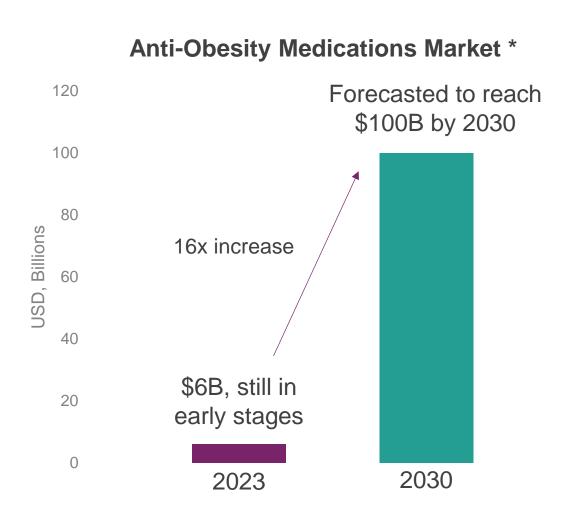
^{*} Clinical timelines are subject to potential regulatory agency review delays

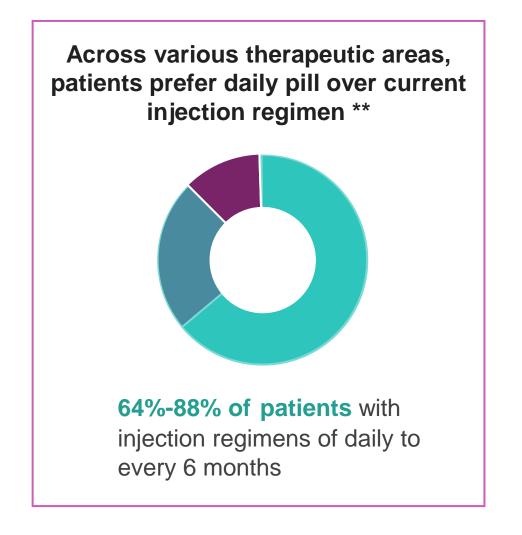
^{**} RT-114 is the subject of a worldwide collaboration with ProGen Co, Ltd.

^{***} Ustekinumab and adalimumab biosimilars are supplied by Celltrion, Inc. Celltrion grants Rani a license and drug supply for each drug.

RT-114: Oral GLP-1/GLP2

Obesity is a Fast-Growing Market; Potential for Oral Options to Play an Important Role







^{*} Why the anti-obesity drug market could grow to \$100 billion by 2030, Goldman Sachs published 30 Oct 2023

^{**} Data aggregated from two third-party surveys commissioned by Rani of U.S. patients (in 2017 for Humira and basal insulin and 2021 for other products). Patients surveyed (n=1,689) were aged 18 years or older and presently used one of Prolia, Humira, basal insulin, Stelara, Cosentyx, Entyvio, Simponi, or Evenity as an injectable biologic to treat a condition.

RaniPill Delivery Technology May Solve for the Shortcomings of Current Orals in Development



Low Bioavailability

Oral chemistry-based formulations demonstrate bioavailability as low as <1% [4]



High API Cost & Supply Chain Issues

Extremely high doses to reach therapeutic effectiveness

- Novo's Oral semaglutide
 350mg per week vs Wegovy
 2.4 mg injectable dose
 (145x higher dose) [5]
- Novo's Oral amycretin and Viking's oral GLP-1/GIP may require **280-350 mg of API/week** to compete [6]



Restrictive Administration Requirements

Restrictive pre-treatment requirements can impact efficacy and patient adherence

- Rybelsus (oral semaglutide) patients instructed to take drug in fasted state as it may increase absorption [7]
- Rybelsus clinical success rate 67% [8]



Inconvenient Dosing Regimen

BID or daily dosing often required to reach therapeutic serum concentrations



Tolerability Risk

Twice-daily Danuglipron (small molecule) discontinued due to tolerability issues and discontinuation rates [9]



Potential Advantages



Significantly better bioavailability than other oral biologic technologies



Significantly less API amount and cost needed than current orals in development



No evidence of food effect so may avoid restrictive administration requirements



Can dose infrequently compared to other orals (weekly or monthly)



Can dose more frequently than SC to limit tolerability issues



Rani's Strategic Vision in the 50 / 50 Partnership with ProGen







OProGen PG-102
GLP-1/GLP-2

Drug-agnostic oral delivery platform for biologics

Long-acting Fc fusion platform for multivalent agonists

Differentiated oral delivery mechanism, with bioavailability comparable to SubQ injection

Differentiated anti-obesity mechanism, with preclinical data showing improved body composition compared with Tirzepatide

Clinically demonstrated equivalent PD to SubQ delivery of GLP-1 through Rani route of administration - at the same dose

Clinically demonstrated favorable safety and differential PK profiles

Versatile delivery platform with broad applicability to address significant opportunities across large market indications in immunology, endocrinology, and beyond

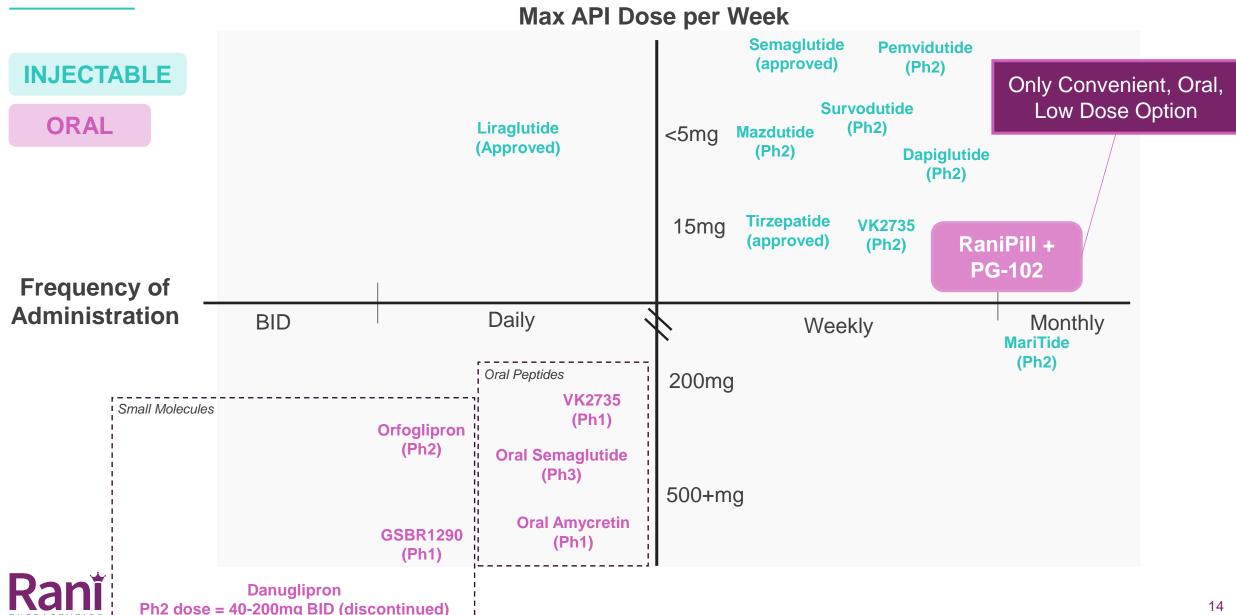
Versatile metabolic benefits with broad applicability to address significant opportunities across broad market indications including T2D, MAFLD/MASH and CVD

Deal Rationale:

- √ Targeting optimized delivery + optimized therapeutic
- ✓ Differentiated oral, low dose, convenient once-weekly GLP-1 / GLP-2 agonist, with potential to preserve lean mass & improve nutrient absorption
- √ Validating preclinical and clinical data



Clear Opportunity in Obesity Landscape for RT-114^[10]



RT-111: Oral Ustekinumab Biosimilar

Advantages of RaniPill Technology in Psoriasis

Other Oral Options

- Less Efficacious than Biologics
 - Otezla, JAK Inhibitors
- Additional Safety Concerns
 - JAK Inhibitors
- Inconvenient Dosing
 - BID Dosing
 - Otezla, JNJ-2113 (testing daily and BID)

Injectables

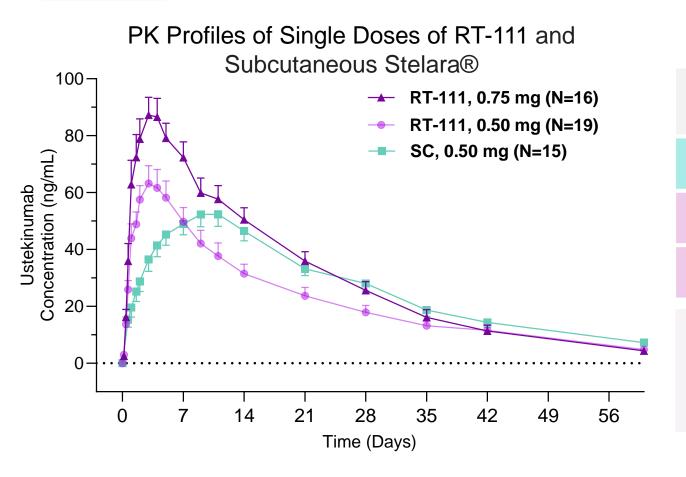
- Inconvenient & Painful to Administer
- Dosing Regimen not Maximizing Clinical Efficacy
- Higher AE Profile
- Significant Penalty for Lapses in Patient Adherence

RaniPill Targets

- Efficacy Comparable to Injectable Biologics
- More Convenient than Other Oral Options
- Potentially Safer Product
- More Forgiving of Lapses in Patient Adherence



RT-111 (Oral Ustekinumab Biosimilar for Psoriasis) Phase 1 Data



Pharmacokinetic Parameters

Group	C _{max} (ng/mL)	T _{max} (days)	AUC _{0-t} (day.ng/mL)	
SC 0.5mg (N=15)	56 ± 4	10 ± 0.8	1,566 ± 130	
RT-111 0.5mg (N=19)	67 ± 7	3.1 ± 0.2	1,315 ± 150	
RT-111 0.75mg (N=16)	92 ± 8	3.3 ± 0.2	1,814 ± 165	

84%

Estimated Bioavailability Relative to SC

Historical Data Shows Potential Opportunity to Improve Efficacy and Safety with Higher Loading Doses

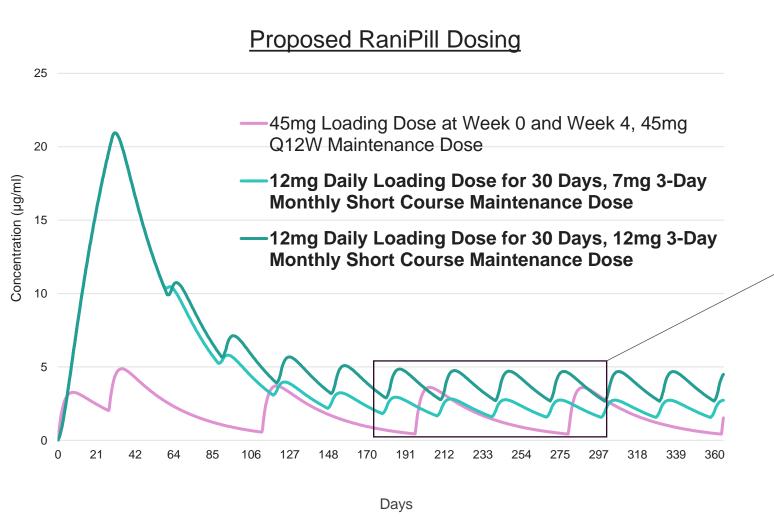
<u>Ustekinumab Efficacy at 12 Weeks*</u>

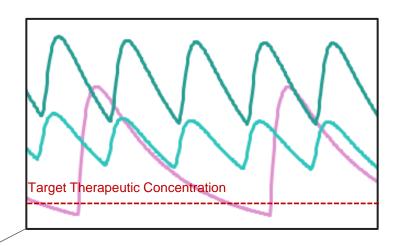
Dose Groups	One 45mg dose	One 90mg dose	Four weekly 45mg dose	Four weekly 90mg dose
75 PASI Score	52%	59%	67%	81%
90 PASI Score	23%	30%	44%	52%
Patients with at least 1 AE	90%	81%	78%	68%



^{*} Data from third party study - N Engl J Med 2007; 356:580-592 DOI: 10.1056/NEJMoa062382, February 8, 2008. Safety data at 20 weeks.

Oral Dosing with the RaniPill Could Enable Higher Loading Doses and Tighter Banding of Therapeutic Concentrations





RaniPill may enable increased frequency of dosing which translates to:

- Lower peak-to-trough variability
- Tighter banding of therapeutic concentrations



Simulation based on ustekinumab published data (see Table 10 of BLA Number 125,261/ Supplement 150 of Janssen Biotech, Inc. submitted to FDA on September 30, 2019).

Target Dosing for RT-111: RaniPill + Ustekinumab

Loading Phase



30-days of 7-12mg Daily Dosing

Potential for better early-onset clinical efficacy

Maintenance Phase



7-12mg 3-day Monthly Short Course

-Total of 36 pills per year per patient

Potential for tighter banding of therapeutic concentration levels





RT-102 Market opportunity

Oral PTH (1-34) for Treatment of Osteoporosis

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

- Significant opportunity for an oral parathyroid hormone option for patients with osteoporosis
- RaniPill could enable oral administration with flexible dosing

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]

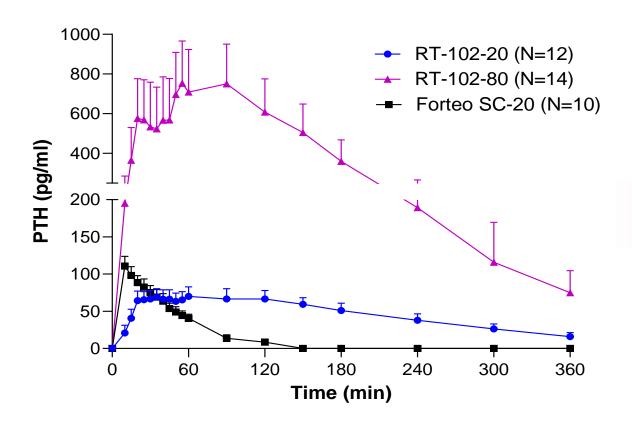
- Potential to grow market with earlier intervention with an oral option
- > Oral option addresses injection aversion

Global PTH market expected to grow to \$2.51B in 2026 at CAGR of 4% with Forteo (teriparatide) earning \$613M in revenue in 2022 [14]



RT-102 (Oral PTH 1-34 for Osteoporosis): Phase I Data

PK Profiles of Single Doses of RT-102



Pharmacokinetic Parameters

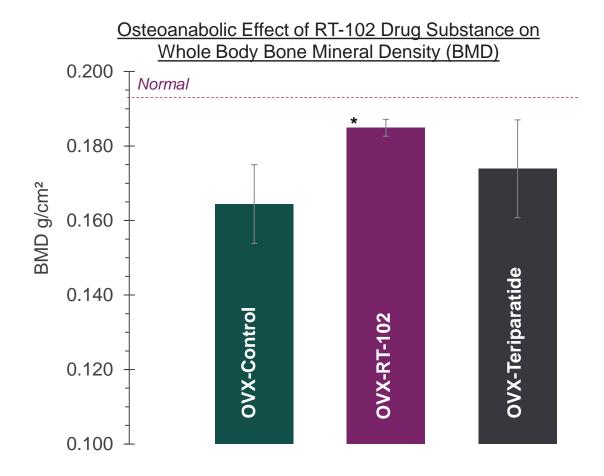
Group	C _{max} (pg/mL)	T _{max} (minutes)	AUC (pg*h/mL)	Bioavailability
Forteo SC 20µg	128 ± 64	13	126 ± 91	
RT-102 20µg	98 ± 35.5	68	343 ± 123	~300%
RT-102 80µg	971 ± 826	60	2600 ± 2410	~400%

Safety & Tolerability:

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



RT-102: Demonstrated Osteoanabolic Effect in Preclinical PD Study



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

Means ± 95% Confidence limits (N=10 per Group)



^{*} p ≤0.05 vs OVX –Controls, ANOVA/ Dunnett's

Anticipated Upcoming Milestones & Progress

Initiate Phase 1 clinical trial with RT-114 in 2025

Advance clinical development of RT-111 at higher doses

Initiate Phase 2 clinical trial with RT-102

Evaluate platform further in strategic areas of focus

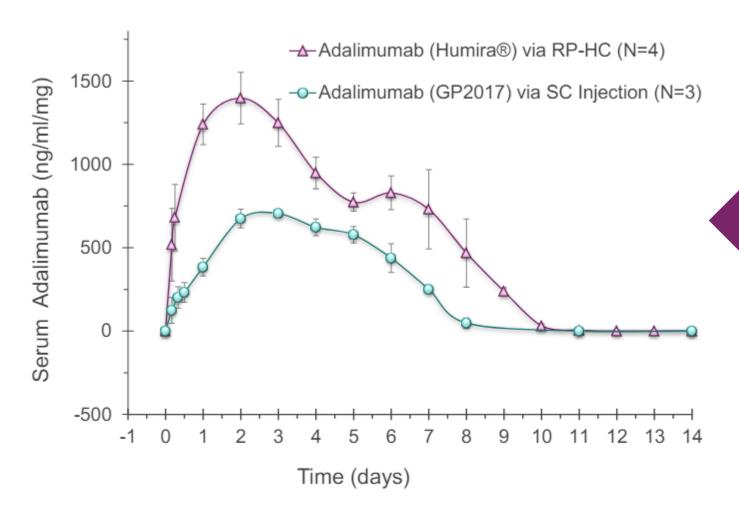






Other Programs: RT-105 Oral Adalimumab RT-110 Oral Long-Acting PTH

PK of Adalimumab via RaniPill HC vs via SC Injection (Dose Normalized)



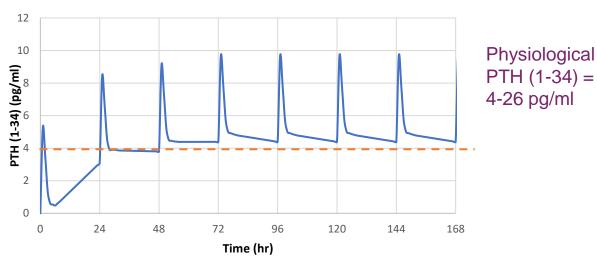
Higher Estimated
Bioavailability via the
RaniPill HC relative to SC
Injection Route





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 [15]
- 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



Demonstrated Equivalent PD to SC through Rani Route of Administration – *At Same Dose*

Objective

 To evaluate the PK-PD profiles of Triagonist (a unimolecular incretin agonist for GLP-1, GIP and Glucagon receptors) in Beagle dogs delivered SC or via endoscopically guided transenteric injection (to mimic the Rani route of administration)

Subjects

Beagles, adult male, 11 - 13 kg, Total N=10

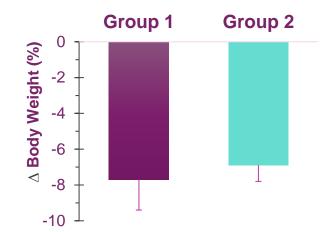
Test Groups

- Group 1 Transenteric (N=5): Triagonist, 0.12mg/kg (0.05ml/kg) injected via endoscopic access
- Group 2 SC (N=5): Triagonist, 0.12mg/kg (0.04ml/kg) injected subcutaneously

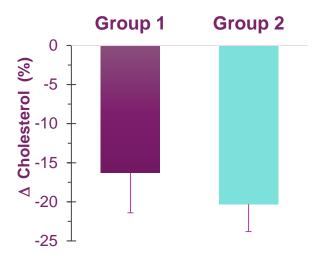
Protocol

- All animals were dosed after an overnight fast
- Over 2 weeks, fasted body weights were taken, and blood samples were serially collected for tracking serum drug concentrations and various PD & safety biomarkers

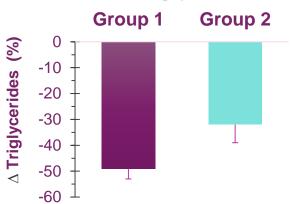
∆ Body Weight (%)



△ Serum Cholesterol (%)



△ Serum Triglycerides (%)

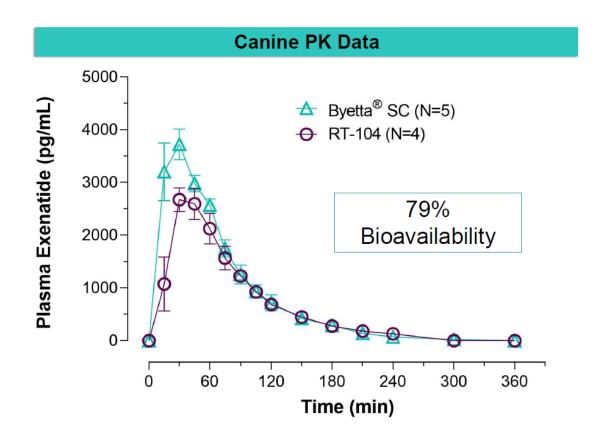


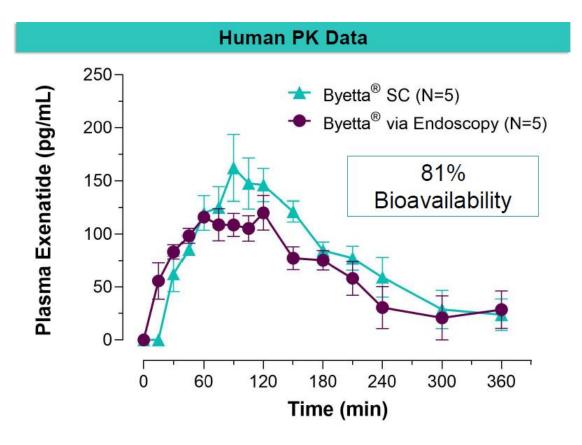
Group 1: Endoscopic

Group 2: SC



Rani Has Demonstrated High Bioavailability of the GLP-1 Agonist Exenatide In Preclinical and Clinical Studies





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

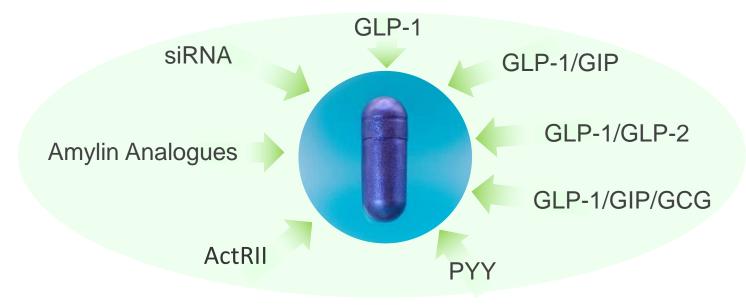


Strategy for RaniPill to Differentiate from Current and Next-Generation Therapies



Modality agnostic

• Potential to deliver single, dual, triagonists orally



Rani Plans to take a Portfolio Approach
With Internal Programs and External Partnerships



Obesity Market Potential Opportunity

	Wegovy	Mounjaro	Retatrutide	Oral Semaglutide	Orfoglipron	Danuglipron	Potential RaniPill Opportunity
Administration	SC	SC	SC	Oral	Oral	Oral	Oral
Frequency	Weekly	Weekly	Weekly	Daily	Daily	Twice Daily	Weekly
Target	GLP-1	Dual Agonist	Triagonist	GLP-1	GLP-1, small molecule	GLP-1, small molecule	Single, Dual and Triagonist
Dosing	2.4mg weekly	15mg weekly	12mg weekly	50mg daily	45mg daily	120mg twice daily	Comparable to SC
Mean Body Weight Loss	15%	21%	24%	15%	15%	NA	Targeting Comparability to SC
Discontinuation	7%	7%	6-16%	6%	10-17%	34%	Targeting Similar to SC

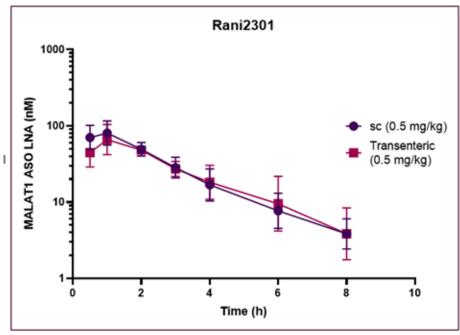
SC = subcutaneous

Significant Potential Opportunity to Capture Portion of Obesity Market Based on Competitive Landscape [11]



Oligonucleotides: Preliminary Research with ASO

ASO Administered VIA Endoscopic Injection that Mimics RaniPill Route of Administration



Geometric mean with geometric SD

PK profiles for Rani route of administration and SC administration were comparable



Key Drivers:

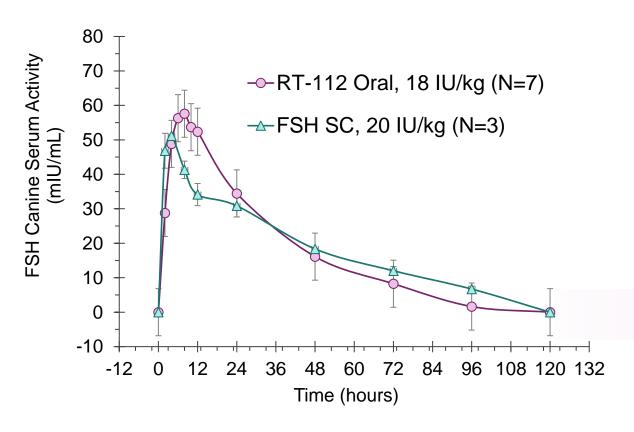
- Emerging area of drug development that offers a promising alternative to therapies targeting downstream processes
- Chemistry attempts at oral delivery have had mixed results in terms of bioavailability

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.[16] 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 [17]
 - Between 2009 and 2016, number of women in the US who froze their eggs rose by more than 1,000% [18]
- 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



Additional Safety Data

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

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

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] Rybelsus U.S. prescribing information, *Pharmacokinetics*.
- [5] For Wegovy, see U.S. prescribing information, Dosage and Administration. For oral semaglutide, Oral semaglutide 50 mg taken once per day in adults with overweight or obesity (OASIS 1): a randomised, double-blind, placebo-controlled, phase trial, Prof Filip K Knop, MD, The Lancet, 25 Jun 2023.
- [6] For oral amycretin, Novo Nordisk's oral amycretin outshines Wegovy in early obesity study, Anna Bratulic, FirstWord PHARMA, 07 Mar 2024. For VK2735 oral, Viking Therapeutics Announces Results from Phase 1 Clinical Trial of Oral Tablet Formulation of Dual GLP-1/GIP Receptor Agonist VK2735, Viking Therapeutics press release, 26 Mar 2024.
- [7] Rybelsus U.S. prescribing information, Indications and Usage.
- [8] 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).
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