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 29, 2021

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** **(Address of principal executive offices)**	**95131** **(Zip Code)**

Registrant's telephone number, including area code: (408) 457-3700

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, par value $0.0001 per share	**RANI**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

Rani Therapeutics Holdings, Inc. (the "Company") is furnishing a copy of an investor presentation (the "Presentation") that the Company intends to use, in whole or in part, during the Company's presentation at the 2021 Cantor Fitzgerald Virtual Global Healthcare Conference on September 30, 2021. The Presentation, including the video content contained therein, can be accessed through the "Investors" section of the Company's website. A copy of the Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

All of the information furnished in this Item 7.01 and Item 9.01 (including Exhibit 99.1) shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Rani Therapeutics Holdings, Inc. Corporate Presentation dated September 2021.
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 hereunto duly authorized.

Rani Therapeutics Holdings, Inc.

Date: September 29, 2021

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

Redefining **Oral Biologics**

September 2021

Rani THERAPEUTICS

Forward-Looking Statements

This presentation and the accompanying oral statements contain forward-looking statements. 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 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, 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, our expectations regarding customer demand for our product candidates, and increased regulatory requirements.

Trade names, trademarks and service marks of other companies appearing in this presentation are the property of their respective owners. Solely for convenience, the trademarks and trade names referred to in this presentation appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

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

The information provided herein is provided to you on the condition that you agree that you will hold it in strict confidence and not reproduce it or disclose it to any third party in whole or in part. This presentation and the accompanying oral presentation also 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.

Today's Presenters

Talat Imran
CEO

Mir Hashim
CSO

Corporate Summary

- Converting injectable biologics into pills
- **$56BN+ initial market opportunity**[1] targeting multiple markets across multiple diseases
- 5 internal development programs
  - Initiation of at least two Phase 1 trials expected in 2022; Repeat-dose study expected in 2022
- Octreotide Phase 1 completed supporting platform safety, tolerability and bioavailability
- Established IP portfolio with 270+ patents filed and 160+ issued/allowed as of 3/24/21

[1] Includes all indications for TNFα inhibitors. Estimated cumulative addressable market for key identified pipeline candidates (octreotide, TNFα antibody, insulin, GLP-1, parathyroid hormone and human growth hormone) per third-party market analyses

Patients Prefer Pills

88%

of RA patients would prefer a daily pill to a bi-weekly injection of Humira

38%

of diabetics miss **4+** injections per week

Frost & Sullivan research report commissioned by Rani

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"Patients initiating treatment with glucagon-like peptide-1 receptor agonists (GLP-1RAs) **had a 71% higher discontinuation rate** in the first 6 months compared with those initiating saxagliptin (oral DPP-4 therapy)"[1]

"The most commonly reported **barrier to maintaining injectable medication was injection concerns** (42%) such as aversion to needles, pain, or needle size."[1]

"The majority of patients (79%) would **prefer a twice-daily oral tablet than an injection** or IV infusion (for rheumatoid arthritis)"[2]

"**Optimal adherence differed significantly** between oral and injectable (93% vs 76%, p< 0.001)"[3]

Sources:

[1] https://www.sciencedirect.com/science/article/pii/S0149291816303757#bib12

[2] https://www.valueinhealthjournal.com/article/S1098-3015(13)03426-8/pdf

[3] https://onlinelibrary.ectrims-congress.eu/ectrims/2017/ACTRIMS-ECTRIMS2017/199728/jonathan.roux.adherence.to.oral.versus.injectable.disease-modifying.therapies.html#:~:text=Mean%20MPR%20was%20higher%20for,%25%2C%20p%3C%200.001).

Rani's Technology

Rani's Development Approach

- **Designed for Minimal Discomfort**
  No small intestine pain receptors
- **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**
  For low cost, high volume manufacturing

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

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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-105	**Psoriatic Arthritis**	**Anti TNF-α Antibody**					Initiate Phase 1 in 2023***
RT-102	**Osteoporosis**	**PTH-OP**					Initiate Phase 1 in 2022***
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 in a proprietary Rani formulation
* Each of these indications will require separate trials
** CCHN will have limited opportunity to negotiate for rights within China
***To follow submission and clearance of IND

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Preclinical & Clinical Experience

Preclinical & Clinical Experience

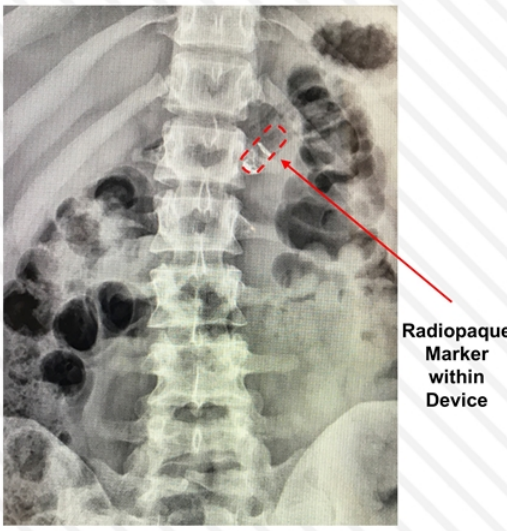
- **Preclinical** – **10 molecules** assessed
  - 4 antibodies, 5 peptides, 1 large protein
  - Awake dogs, anesthetized juvenile pigs
  - Single and repeat-dose studies
    - No serious adverse events observed to date
    - High bioavailability, comparable to parenteral injections

- **Clinical – 3 molecules** assessed**, 5 human clinical studies** in healthy volunteers
  - RaniPill™ platform-only study
  - Phase I study with RaniPill and biologic (octreotide)
  - 3 studies simulating Rani delivery via Endoscopic intrajejunal injections
  - 2 peptides,1 antibody
    - No serious adverse events observed to date
    - High bioavailability, comparable to injections

Safety and Tolerability Study of RaniPill Platform in Humans

- Study conducted in 2018
- RaniPill device tracked by X-ray imaging
- RaniPill device without a needle in fasted and fed groups
  - N=10 per group
- No food effect observed on device functionality
- RaniPill was well-tolerated by all subjects
- No serious adverse events were reported
- Met all safety endpoints
  - Ability to swallow
  - No sensation upon deployment
  - Ability to pass capsule remnants

X-Ray Image of Intact RaniPill



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RaniPill Repeat Administration Canine Study

Study Overview

***Objective*:**
Evaluate safety and tolerability of once-daily 7 day repeat oral administration of the RaniPill capsule

***Animal Model*:**
Male and female beagles naïve to all drugs

***Study Groups*:**
Test Group:
Orally administered RaniPill capsule, containing octreotide, once a day for 7 days, followed by a 7 day wash-out period; n = 8 (4 males, 4 females)
Control Group:
Orally administered enteric coated size 000 capsule, containing sugar once a day for 7 days, followed by a 7 day wash-out period; n = 4 (2 males, 2 females)

Histopathology

Animals necropsied at end of the study:
Postmortem examination (excluding brain) was performed in 12 dogs (Test = 8, Control = 4) on Day 14 ± 1

Samples of small intestine from each animal (duodenum n = 1, jejunum n = 3, ileum n = 1) were collected for histopathological evaluation

Histological evaluation included an assessment and semi-quantitative scoring of lesions such as inflammation, hemorrhage, necrosis and fibrosis/fibroplasia

Summary

The RaniPill capsules were well-tolerated in all animals

No significant gastrointestinal abnormalities were associated with oral administration of the RaniPill capsule

No clinically adverse observations were noted

Phase I Study with the RaniPill Containing Octreotide

COMPLETED	Q4 2019
Subjects	Healthy men and women, aged 18-55 years
Design	Open label, single center (Australia)
Test Articles	RaniPill Devices: 3 versions with incremental balloon sizes, each containing 100 µg of octreotide
1 Control Arm (N=6)	IV Injection of 100 µg of octreotide (*Sandostatin*®)
3 Treatment Arms (N=52)	3 cohorts of RaniPill devices with incrementally sized balloons
Primary Endpoints	Safety and Tolerability of the RaniPill capsule
Secondary Endpoint	Bioavailability of octreotide delivered via the RaniPill capsule

Phase I Primary Endpoints: Safety and Tolerability

- Octreotide-RP capsule was well-tolerated by all subjects
- No subject had difficulty swallowing the capsule
- Capsule remnants passed out in all subjects
- No serious adverse events noted in the study

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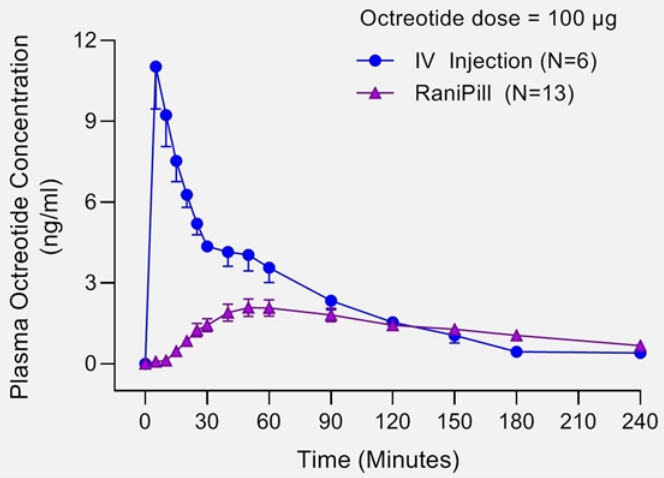
Pharmacokinetic Data: RT-101 Phase I Study



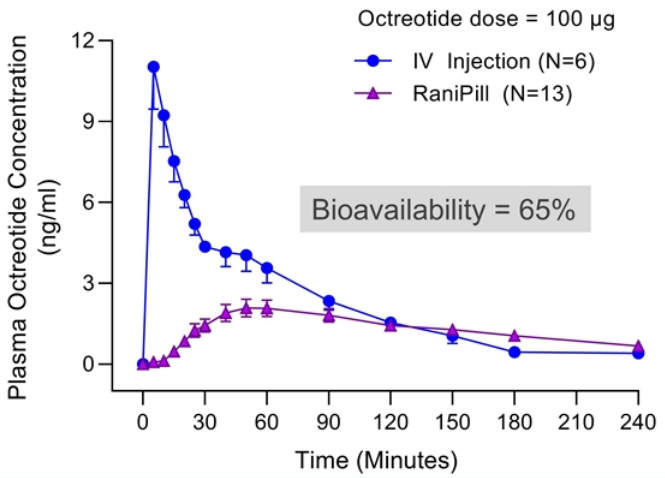
Bioavailability = 65%

RaniPill delivered Octreotide

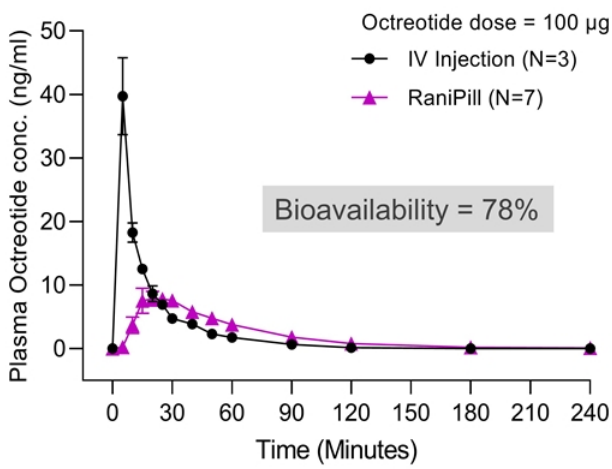
with high bioavailability

Canine Model Could Be Predictive of Human PK Data

HUMAN



CANINE

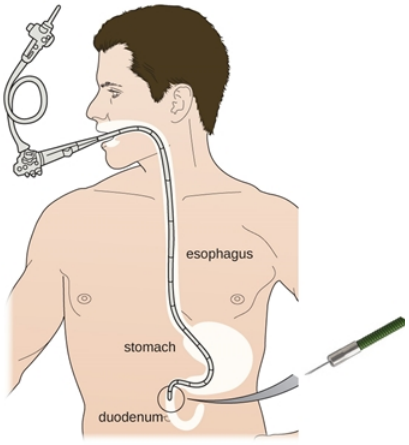


Preclinical Data from Canine Model May Translate Well to Human Clinical Development

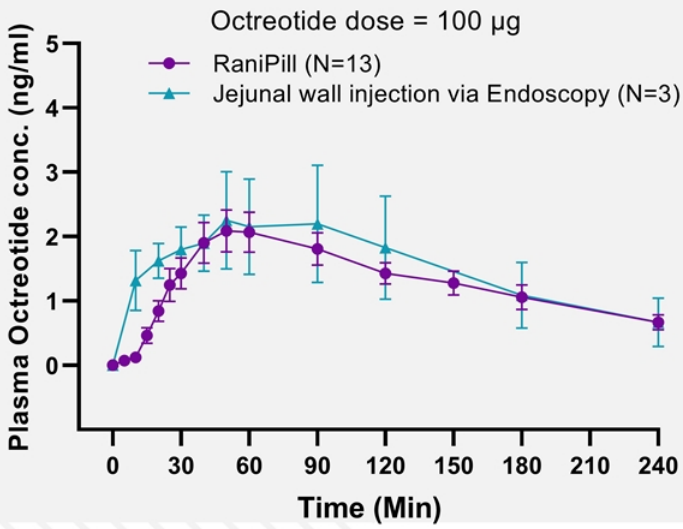
Additional Human Studies

Endoscopic Intrajejunal Administration in Humans

- Objective: to obtain an early read on the PK profile via Rani route in humans
- Methods: Using an endoscopic approach, an approved drug (commercial formulation) is injected into the jejunal wall (IJ route) to mimic the Rani route of administration
- We have determined PK of three drugs in these type of studies
  - Sandostatin (octreotide)
  - Byetta (exenatide)
  - Humira (adalimumab)



PK Data of Octreotide with Endoscopic Injections vs. Oral RaniPill



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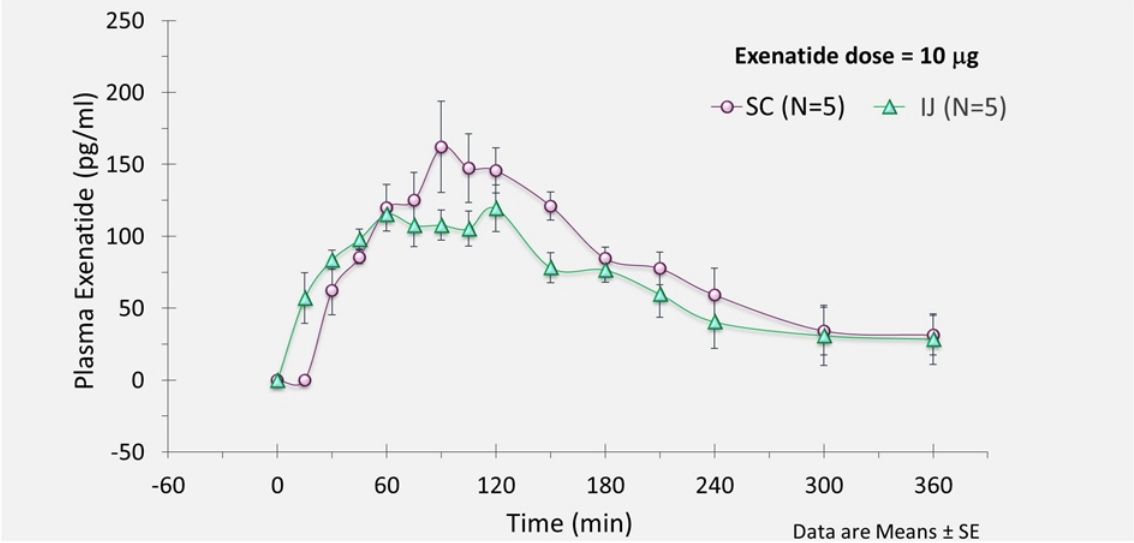
Endoscopic Intrajejunal Administration of Exenatide (GLP-1 Analog) in Humans

PK in Healthy Subjects - SC vs. Intrajejunal (IJ)



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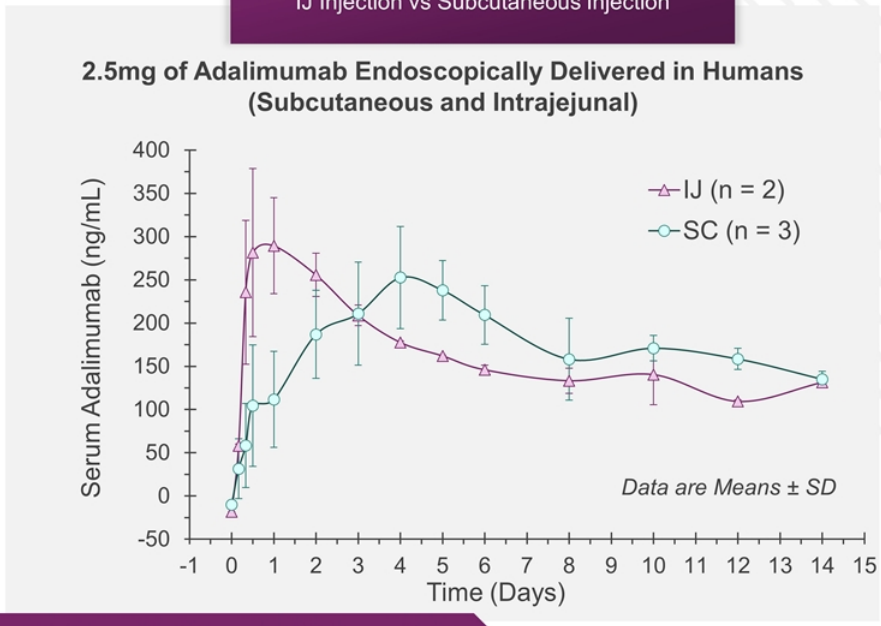
Endoscopic Intrajejunal Administration of Anti TNF-α Antibody in Humans

Humira
IJ Injection vs Subcutaneous Injection



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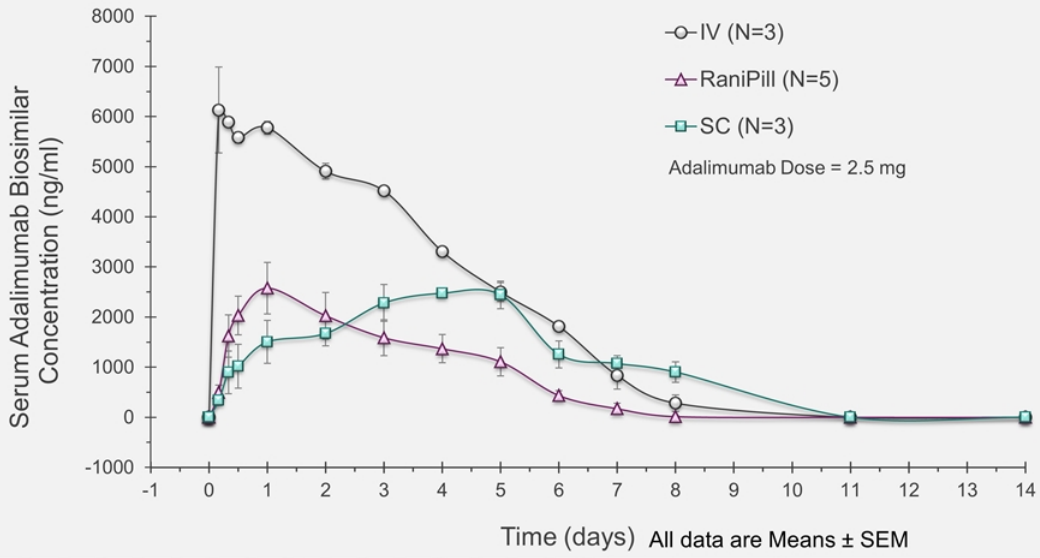
Adalimumab: Phase 1 Initiation – 2023

*Back Bay Report 2018, projected peak revenue

Additional Preclinical Studies

PK of Oral Adalimumab Biosimilar in Awake Dogs



BIOAVAILABILITY* (%)

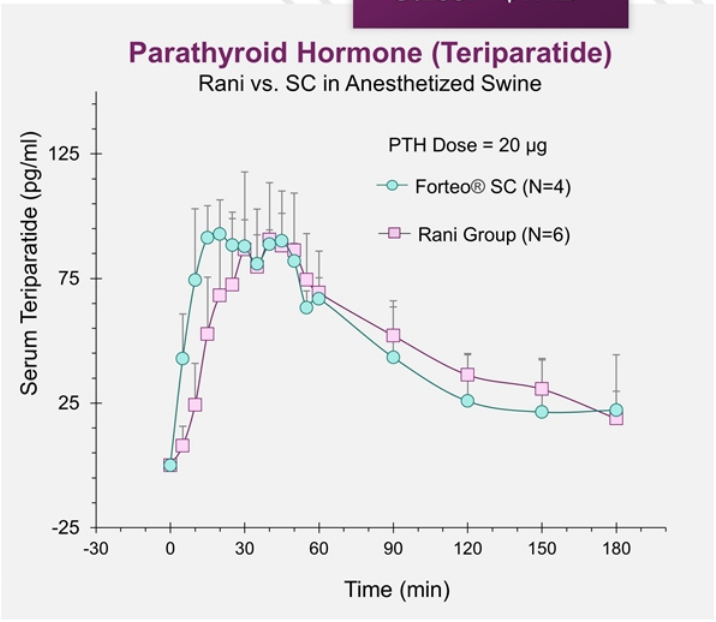
SC	46 ± 3
Rani	49 ± 6

**Formation of anti-adalimumab antibodies in the canine impacted the accurate determination of bioavailability*

RT-110/102 - PTH (Teriparatide)

Estimated Combined Peak Sales: ~$1.4B*

- Used in two indications:
  - Osteoporosis (OP) and
  - Hypoparathyroidism (Hypo) (rare disease)
- Must be injected daily
- PTH Market has been stable at ~$2.0B
  - Affects ~10M adult patients in the United States
  - Prevalence increasing due to aging population
  - An oral Teriparatide could dramatically increase the market
  - Teriparatide-based long-acting product demonstrated to be superior (Ascendis). Rani is working to create an oral form
  - Potential multi-billion global market



PTH-OP: Phase 1 Initiation – 2022 | PTH-Hypo: 2023

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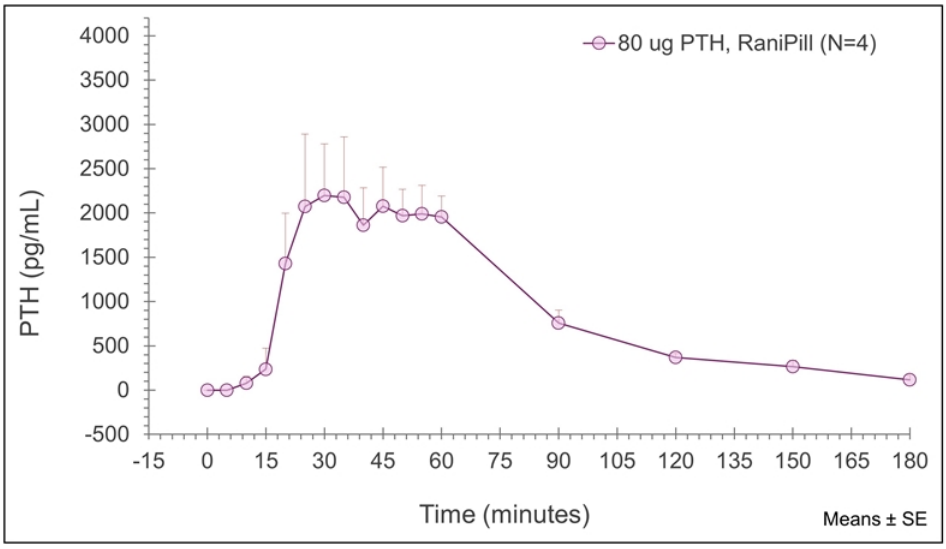
*Back Bay Report 2019, combined OP and Hypo

PK of Oral Teriparatide at 80 µg in Awake dogs

Early Preclinical Data



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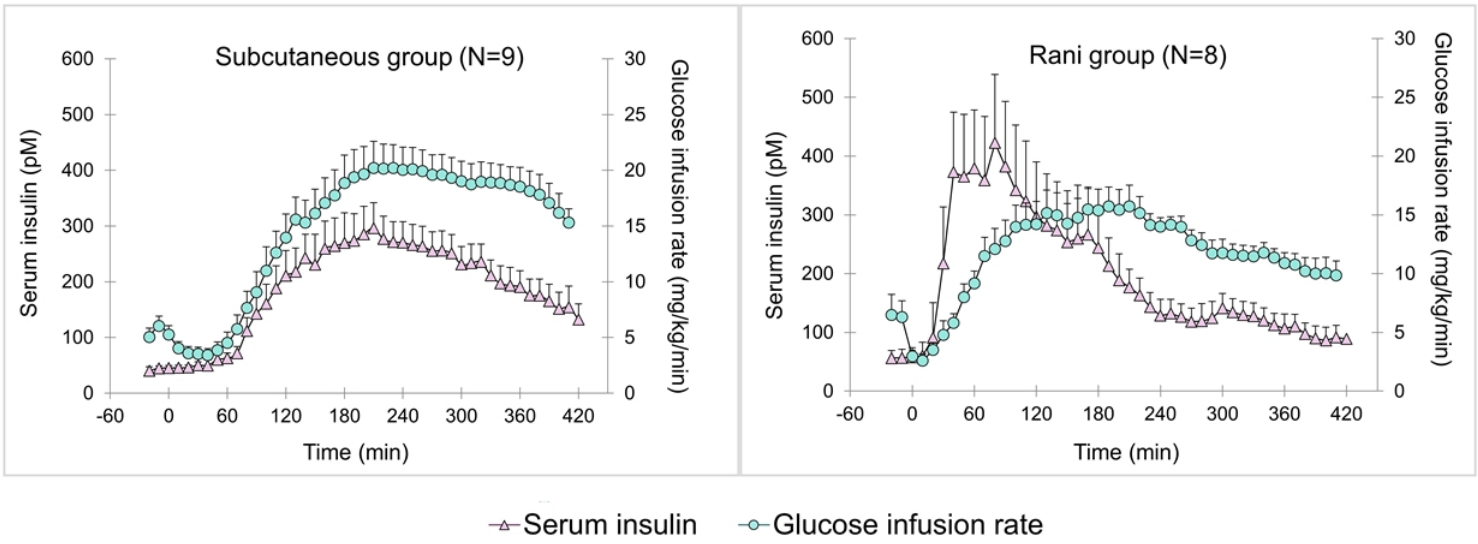
Insulin PK/PD in Juvenile Swine

Insulin dose = 20 IU



Regulatory Strategy & Key Milestones

Regulatory Strategy

Based on Pre-submission Meeting with FDA's CDRH

IDE study to evaluate safety & reliability of the RaniPill

- 40 healthy adults, 18-50 years old
- Dosing for 8 weeks
- Using non-drug tracer

Clinical Studies for Each Drug

RaniPill Master File

CDRH
Center for Devices and Radiological Health

FDA

CBER/ CDER

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Key Near Term Milestones

DEVELOPMENT PROGRAM	INDICATION	DESCRIPTION	PLANNED TIMING*
RT-101	NETs / Acromegaly	Repeat Dose Platform Study	2022
RT-102	Osteoporosis	Initiate Phase 1 Clinical Trial	2022
RT-109	GH Deficiency	Initiate Phase 1 Clinical Trial	2022
RT-105	Psoriatic Arthritis	Initiate Phase 1 Clinical Trial	2023
RT-110	Hypo-parathyroidism	Initiate Phase 1 Clinical Trial	2023

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*Timelines are subject to regulatory agencies submission and clearance

Thank You

Rani
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