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): February 05, 2024

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 7.01 Regulation FD Disclosure.

On February 5, 2024, Rani Therapeutics Holdings, Inc. (the "Company" or "Rani") issued a press release to announce topline results from the RT-111 Phase 1 clinical trial. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The Company is also furnishing 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 furnished as Exhibit 99.2 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 and Exhibit 99.2) 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 8.01 Other Events.

On February 5, 2024, Rani announced topline results from the RT-111 Phase 1 clinical trial.

Study Design

A single-center, open-label Phase 1 study of RT-111, a RaniPill capsule containing ustekinumab biosimilar, was conducted in Australia. The study evaluated the safety and tolerability of a single administration of RT-111 in healthy adult volunteers. Of the 55 participants, 20 orally ingested RT-111 containing a single 0.5mg dose of ustekinumab biosimilar and 20 orally ingested RT-111 containing a single 0.75mg dose of ustekinumab biosimilar, while a control group of 15 participants received a single 0.5mg subcutaneous (SC) injection of STELARA® (ustekinumab), a commercial formulation of ustekinumab.

Participants were fasted overnight prior to dose administration. Blood samples were collected at various time points over 60 days and analyzed for ustekinumab concentrations. Blood samples were analyzed for anti-drug antibodies at three timepoints.

Topline Results

Safety and Tolerability

- RT-111 was generally well tolerated, with no serious adverse events (SAEs) noted during the study
  - o None of the participants withdrew from the study due to any adverse event
  - o Two subjects in the 0.5mg RT-111 group and one subject in the 0.5mg SC STELARA® group had mild, transient adverse events which resolved without any intervention
- There was no meaningful difference in incidence of anti-drug antibodies via the RaniPill route of delivery compared to STELARA® SC injection

		Stelara® SC 0.50 mg N=15	RT-111 0.50 mg N=20	RT-111 0.75 mg N=20
Drug Signal Detected		N=15	N=19	N=16
	Number of ADA Positive Cases			
Total ADA Positive*	N	4	2	6
	%	27%	11%	38%

* ADA positive post dosing, increase in titer compared to pre-dose level

- No participants reported difficulty swallowing the capsule and capsule remnants passed from all participants without sequelae

Pharmacokinetics

- Oral RT-111 delivered 0.5mg and 0.75mg of ustekinumab biosimilar with high bioavailability (estimated bioavailability of 84% for 0.5mg RT-111 relative to 0.5mg SC STELARA®).

	Stelara® SC 0.50mg	RT-111 0.50mg	RT-111 0.75mg
Cmax (ng/mL)	56 ± 4	67 ± 7	92 ± 8
Tmax (days)	10 ± 0.8	3.1 ± 0.2*	3.3 ± 0.2*
AUC (day*ng/mL)	1,566 ± 130	1,315 ± 150	1,814 ± 165
Bioavailability	--	84%	--

Data are Mean ± SE from all subjects, including those with anti-drug antibodies. *p<0.0001 significantly different from SC group.

This report contains "forward-looking" statements, including statements regarding topline results from the RT-111 Phase 1 study. Actual results may differ materially from those set forth in this report due to the risks and uncertainties inherent in research and development, including the risk that initial (or topline) clinical results do not report on all data from a clinical trial that may be important for development or regulatory approval, the risk that results from earlier clinical trials may not be indicative of future clinical results, as well as other risks detailed in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 as well as discussions of potential risks, uncertainties and other important factors in the Company's other filings with the U.S. Securities and Exchange Commission. The Company undertakes no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release of Rani Therapeutics Holdings, Inc. dated February 5, 2024
99.2	Presentation dated February 2024
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: February 5, 2024

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

Rani Therapeutics Announces Positive Topline Results from Phase 1 Study of

an Oral Anti-Interleukin 12/23 Antibody (RT-111)

- RT-111 achieved high bioavailability in humans -

- RT-111 was well-tolerated, with no serious adverse events -

- Celltrion has right of first negotiation to acquire worldwide rights to RT-111 following a Phase 1 clinical trial that meets its primary endpoints –

- Rani has now successfully completed three Phase 1 trials using RaniPill® technology -

- Company to host conference call today at 8:30 a.m. ET / 5:30 a.m. PT –

SAN JOSE, Calif., February 5, 2024 -- 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 positive topline results from its Phase 1 clinical study of RT-111, a RaniPill® capsule containing an ustekinumab biosimilar, CT-P43. In the study, RT-111 was well-tolerated and delivered ustekinumab with high bioavailability.

"We are highly encouraged by the positive results from our Phase 1 study for RT-111 – our third successfully completed Phase 1 trial using RaniPill® technology. To our knowledge, RT-111 is the first ever oral monoclonal antibody to achieve high bioavailability in humans," said Talat Imran, Chief Executive Officer of Rani. "These data provide clinical validation of our ability to successfully transform an injectable large molecule into an oral pill. Specifically for this program, we believe RT-111 has the potential to offer a highly differentiated dosing regimen for patients with psoriasis compared to both injectable biologics and oral small molecules and peptides. The success of the Phase 1 study of RT-111 marks another significant milestone for the Rani team, as we diligently work towards making oral biologics a reality for the millions of patients living with autoimmune conditions."

Ustekinumab is a human IgG1κ monoclonal antibody that binds with specificity to the p40 protein subunit used by both the interleukin-12 and interleukin-23 (IL-12 and IL-23) cytokines. Currently, ustekinumab is available only as a subcutaneous injection (SC) and is marketed in the United States by Janssen as STELARA® for the treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, moderate to severe Crohn's disease, and moderate to severe ulcerative colitis, all of which have large unmet medical needs for oral treatment. Sales for STELARA were approximately $6.4 billion in the United States and approximately $9.7 billion worldwide in 2022.

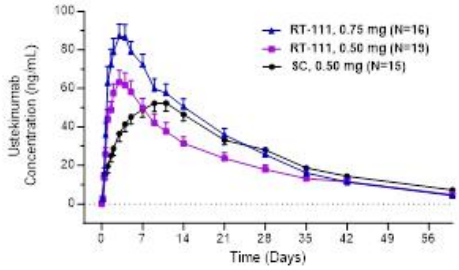
Rani's single-center, open label, Phase 1 study of RT-111 was conducted in Australia. The study evaluated the safety, tolerability, and pharmacokinetics (PK) of RT-111 in healthy adult volunteers. The study enrolled 20 participants each in RT-111 0.5mg and 0.75mg dose groups, and 15 participants in a STELARA (ustekinumab) 0.5mg subcutaneous (SC) injection group.

Phase 1 Topline Results

Pharmacokinetics

- Oral RT-111 delivered ustekinumab biosimilar in a dose proportional manner and with high bioavailability (estimated at 84% relative to subcutaneous injection).
- Oral RT-111 demonstrated a higher Cmax and shorter Tmax compared to ustekinumab delivered by SC injection (0.5mg).

Pharmacokinetics of Ustekinumab (CT-P43)
Oral (RT-111) vs SC Injection



	Stelara® SC 0.50mg	RT-111 0.50mg	RT-111 0.75mg
Cmax (ng/mL)	56 ± 4	67 ± 7	92 ± 8
Tmax (days)	10 ± 0.8	3.1 ± 0.2*	3.3 ± 0.2*
AUC (day*ng/mL)	1,566 ± 130	1,315 ± 150	1,814 ± 165

Data are Mean ± SE from all subjects, including those with anti-drug antibodies. *p<0.0001 significantly different from SC group.

- RT-111 was well-tolerated by all participants in the two RT-111 groups, and no serious adverse events were observed in the study.
- There was no meaningful difference in incidence of anti-drug antibodies (ADA) via RaniPill® route of delivery, compared to STELARA® SC injection
- No participants reported difficulty swallowing the capsule and capsule remnants passed from all participants without sequelae.

The ustekinumab biosimilar used in RT-111 is manufactured and supplied by Celltrion, Inc. (“Celltrion”) under Rani’s License and Supply Agreement with Celltrion announced in January 2023. Under that agreement, Celltrion exclusively supplies to Rani the ustekinumab biosimilar drug substance (CT-P43) required for RT-111. Rani is granted an exclusive license to use CT-P43 in the development and commercialization of RT-111, and Celltrion is granted a right of first negotiation to acquire worldwide rights to RT-111 following a Phase 1 clinical trial that meets its primary endpoint(s).

Conference Call

Rani will host a corresponding conference call and live webcast at 8:30 a.m. ET / 5:30 a.m. PT on February 5, 2024, to discuss the results from its Phase 1 clinical trial of RT-111. Individuals interested in listening to the live conference call may do so by using the webcast link in the “Investors” section of the company’s website at www.ranitherapeutics.com. A webcast replay will be available in the investor relations section on the company’s website for 90 days following the completion of the call.

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 has successfully conducted several preclinical and clinical studies to evaluate safety, tolerability and bioavailability using RaniPill® capsule technology. For more information, visit www.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 for RT-111 to be an alternative oral treatment option compared to burdensome injectables for autoimmune conditions, and the potential for Rani to make oral biologics a reality for millions of patients living with autoimmune conditions. 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 "intend" and "potential" 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

February 2024

NASDAQ: RANI

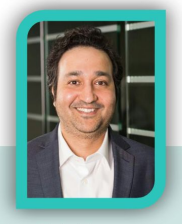
Forward-Looking Statements

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 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.

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.

This presentation and the accompanying oral statements 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.

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.



Talat Imran
Chief Executive Officer

Svai Sanford
Chief Financial Officer

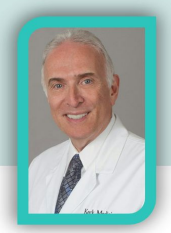
Mir Hashim, Ph.D.
Chief Scientific Officer

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 THERAPEUTICS

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

FOCUS: Oral Delivery of Biologic Drugs with Bioavailability Comparable to Parenteral Products

TECHNOLOGY:

GO
- 3mg Capacity
- Solid Drug Formulation

HC (High Capacity)
- 200 µL Capacity
- Liquid Drug Formulation

PIPELINE: Immunology & Endocrinology

DISCOVERY: Obesity, Nanobodies, Hemophilia, Bispecific MABs, Fertility

425+ Patent Applications, 225+ Granted Patents

Development Pipeline

	INDICATION(S)	FORMULATION	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	KEY MILESTONE*
CORE PROGRAMS							
RT-111	Psoriasis	Ustekinumab**					Phase 1 Study Completed
RT-102	Osteoporosis	PTH-OP					Initiate Phase 2 in 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

Rani THERAPEUTICS

Development Pipeline

	INDICATION(S)	FORMULATION	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	KEY MILESTONE*
CORE PROGRAMS							
RT-111	**Psoriasis**	**Ustekinumab****					**Phase 1 Study Completed**
RT-102	Osteoporosis	PTH-OP					Initiate Phase 2 in 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

Rani THERAPEUTICS

RT-111 Phase 1 Study Data

Study Overview

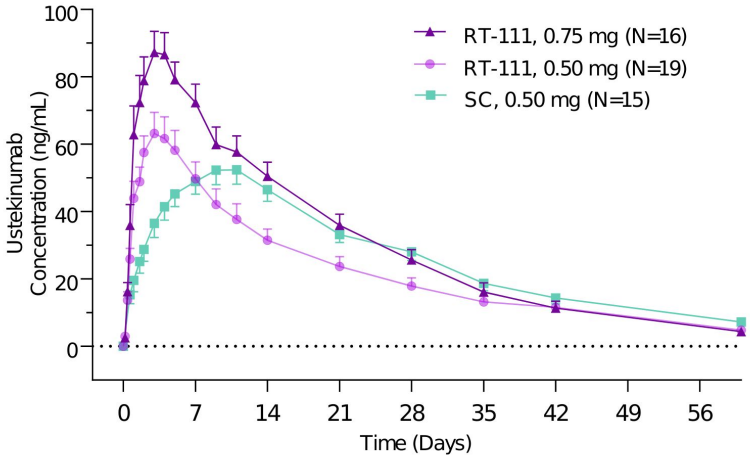
A Phase 1 Study to Evaluate the Safety, Tolerability and Pharmacokinetics (PK) of RT-111 – RaniPill Capsule Containing Ustekinumab (CT-P43) – Administered Orally to Healthy Volunteers	
Objective	To assess safety, tolerability and PKof Ustekinumab delivered via Oral RaniPill
Study Population	Healthy men and women volunteers recruited from the general population
Study Site	Single site in Australia
End Points	PK parameters, safety and tolerability

Study Design: Single Ascending Doses

- **Study Groups**
  - Control Group: 0.50 mg Stelara SC (N=15)
  - RT-111 Group: 0.50 mg CT-P43 in RaniPill (N=20)
  - RT-111 Group: 0.75 mg CT-P43 in RaniPill (N=20)
- **Protocol**
  - Participants were given a single dose of the study drug (SC or Oral) after an overnight fast
  - Blood samples were collected at various time points over 60 days and analyzed for ustekinumab concentrations
  - Blood samples were analyzed for anti-drug antibodies at 3 timepoints
  - Excretion of device remnants confirmed with imaging

Pharmacokinetics

PK Profiles of Oral Ustekinumab Biosimilar (RT-111) vs SC Stelara Injection



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

Rani THERAPEUTICS

Data shown are Mean ± SE, Data pending final QA review. Estimated bioavailability based on 0.5mg dose

Safety & Tolerability

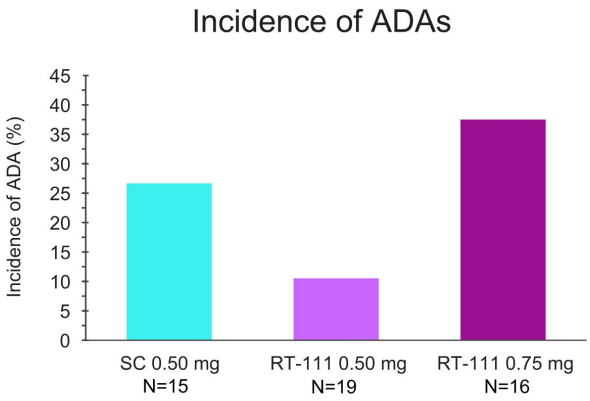
Incidence of Adverse Events

	Adverse Events	SC, 0.50 mg (N=15)	RT-111, 0.50 mg (N=20)	RT-111, 0.75 mg (N=20)
	All	1	2	0
Drug-Related	Abdominal Bloating	0	1 (5%)	0
	Injection Site Rash/Reaction	1 (6.7%)	0	0
RaniPill-Related	Burning Sensation in stomach*	N/A	1 (5%)	0

*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.

Incidence of Anti-Drug Antibodies (ADAs)

		Stelara SC 0.50 mg N=15	RT-111 0.50 mg N=20	RT-111 0.75 mg N=20
Drug Signal Detected		N=15	N=19	N=16
	Number of ADA Positive Cases			
Total ADA Positive*	N	4	2	6
	%	27%	11%	38%



*ADA positive post dosing, increase in titer compared to pre-dose level

Summary

RT-111 was well-tolerated No SAEs

Oral delivery of Ustekinumab biosimilar via RaniPill with High Bioavailability

No meaningful difference in ADA development via Rani route of delivery compared to SC injection

RT-111 Oral Ustekinumab
Target Product Profile

Psoriasis Competitive Landscape – Select Injectables(1)

	Humira	Cosentyx	Taltz	Tremfya	Skyrizi	Stelara	Potential RaniPill Opportunity
Administration	SC	SC	SC	SC	SC	SC	Oral
Maintenance Frequency	Q2W	Q4W	Q4W	Q8W	Quarterly	Quarterly	3-Day Monthly Short Course
Target	TNF-α	IL-17A	IL-17A	IL-23	IL-23	IL-12/IL-23	IL-12/IL-23
Revenue*	$21.2B	$4.8B	$2.5B	$2.7B	$5.2B	$9.7B	--
Total Number Annual SC Injections	26	13-26	13	6-7	4	4	0
48-60 Week % Patients PASI 75**	63%	74%	74-83%	88%	92%	89%	Efficacy Similar to Injectable
12 - 16 Week % Patients PASI 75**	71-78%	75-87%	87-90%	83-91%	87-89%	66-76%	Targeting 81+%

SC = subcutaneous

* Product revenue from all indications in 2022.

** Data do not represent head-to-head studies.

Significant Potential Opportunity to Capture Portion of Psoriasis Market Based on Improvement in Convenience and Potential Improved Efficacy

Psoriasis Competitive Landscape – Select Orals(2)

	Otezla	Sotyktu	JNJ-2113*** (PTG-200)	Potential RaniPill Opportunity
Frequency	BID	Daily	QD / BID	3-Day Monthly Short Course
Target	PDE4	TYK2	IL-23	IL-12/IL-23
Revenue*	$2.2B	$.1B (Q1-Q3 2023)	NA	--
Total Number of Pills	730	365	365 / 730	36
52 Week % Patients PASI 75**	61%	72.6%	NA	Efficacy Similar to Injectable
12 - 16 Week % Patients PASI 75**	33%	61%	65% / 79%	Targeting 81+%

* Product revenue from all indications in 2022. unless otherwise indicated.
** Data do not represent head-to-head studies.
*** Not yet approved.

Significant Potential Opportunity to Capture Portion of Psoriasis Market Based on Improvement in Convenience and Potential Improved Efficacy

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

Ustekinumab Efficacy at 12 Weeks*

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%

Rani THERAPEUTICS

* 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.

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

Ustekinumab Efficacy at 12 Weeks*

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%

Rani THERAPEUTICS

* 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.

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

Ustekinumab Efficacy at 12 Weeks*

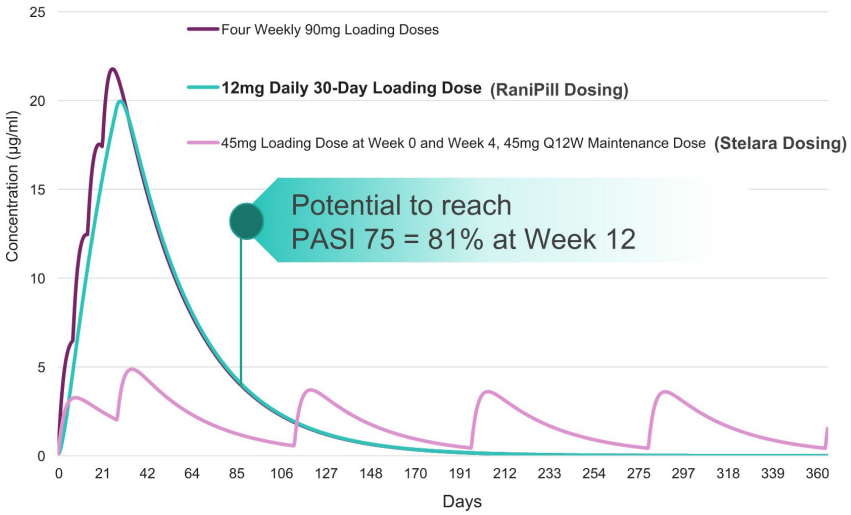
Dose Groups	One 45mg dose	One 90mg dose	Four weekly 45mg dose	Four weekly 90mg dose
75 PASI Score	52%	59%	67%	81%
90 PASI Score	23%	30%	44%	52%
Patients with at least 1 AE	90%	81%	78%	68%

Rani THERAPEUTICS

* 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.

The RaniPill Could Enable Higher Loading Phase Doses with the Convenience of Oral Administration

Simulated RaniPill+Ustekinumab Loading Dose Serum Concentrations at 12 Weeks

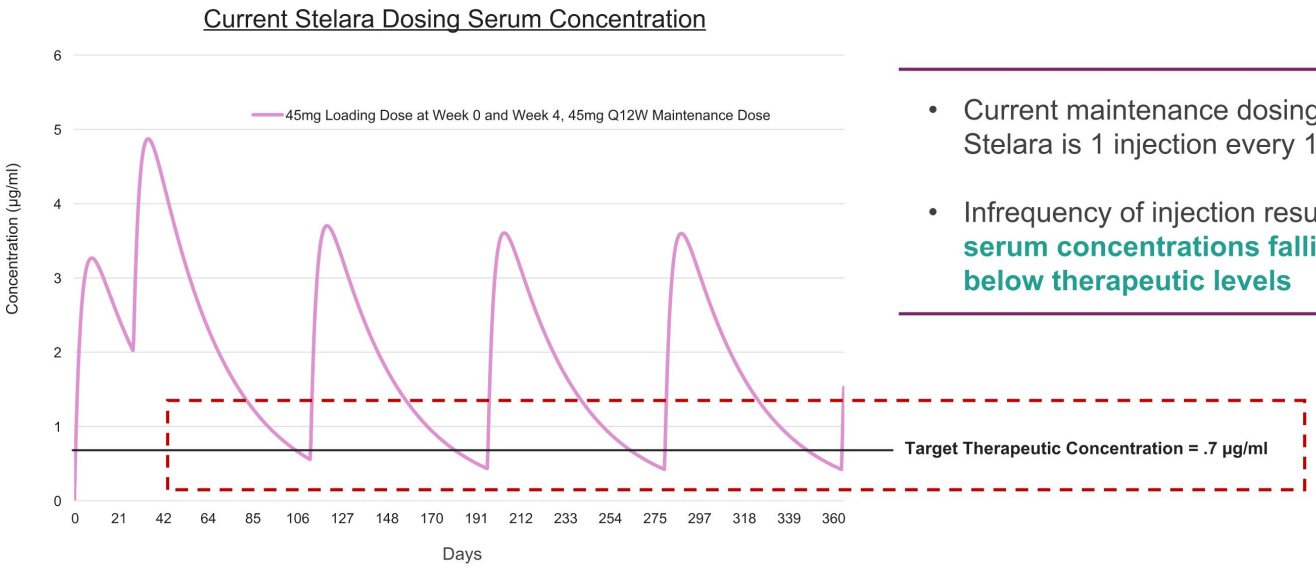


Daily Oral Administration with RaniPill Could Deliver Higher Loading Dose Regimen

Potential for Better Treatment of Acute Flare Ups at the Start of Therapy

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).

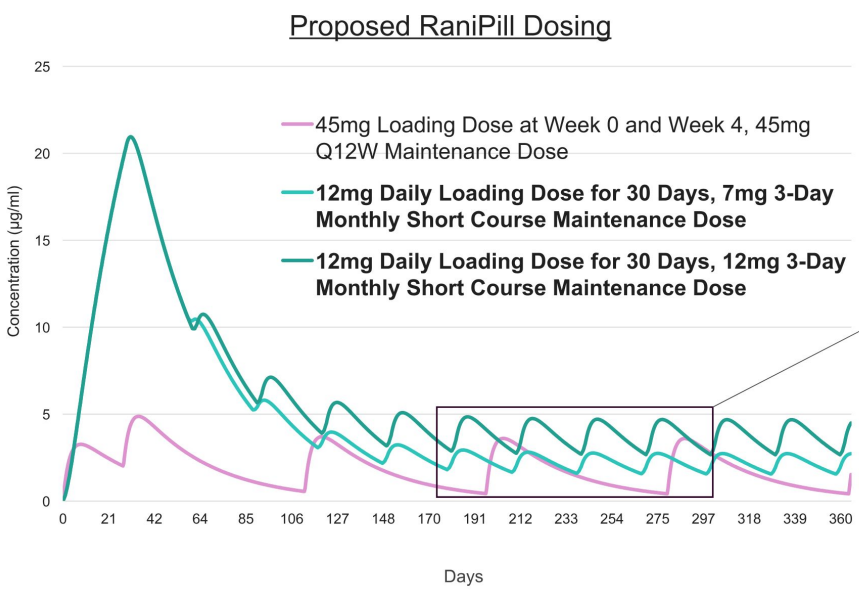
Current Stelara Maintenance Phase

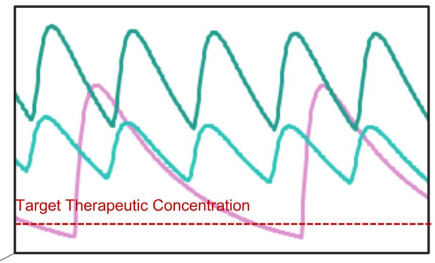


- Current maintenance dosing for Stelara is 1 injection every 12 weeks
- Infrequency of injection results in **serum concentrations falling below therapeutic levels**

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).

RaniPill + Ustekinumab Proposed Maintenance Dosing





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: RaniPill + Ustekinumab

Loading Phase

DAILY

30-days of 7-12mg Daily Dosing

- Potential for better early-onset clinical efficacy

Maintenance Phase

MONTHLY

7-12mg 3-day Monthly Short Course

–*Total of 36 pills per year per patient*

- Potential for tighter banding of therapeutic concentration levels

Rani THERAPEUTICS

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
    - Protagonist, Otezla

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

Celltrion Supply Agreement Includes ROFN

Ustekinumab Biosimilar (RT-111)

- **Lead Indication:** Psoriasis
- **Market Size:** $9.7B in Stelara (ustekinumab) sales worldwide in 2022 (3)

Adalimumab Biosimilar (RT-105)

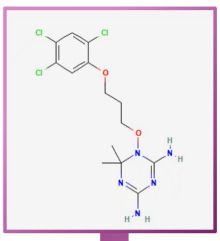
- **Lead Indication:** Psoriatic Arthritis
- **Market Size:** $21.2B in Humira (adalimumab) sales worldwide in 2022 (4)

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

Target Product Profile of RaniPill Products



- Efficacy
- Long Half-Life
- Safety

Of a Monoclonal Antibody

- Convenience
- Dosing Flexibility
- Patient Preference

Of a Pill

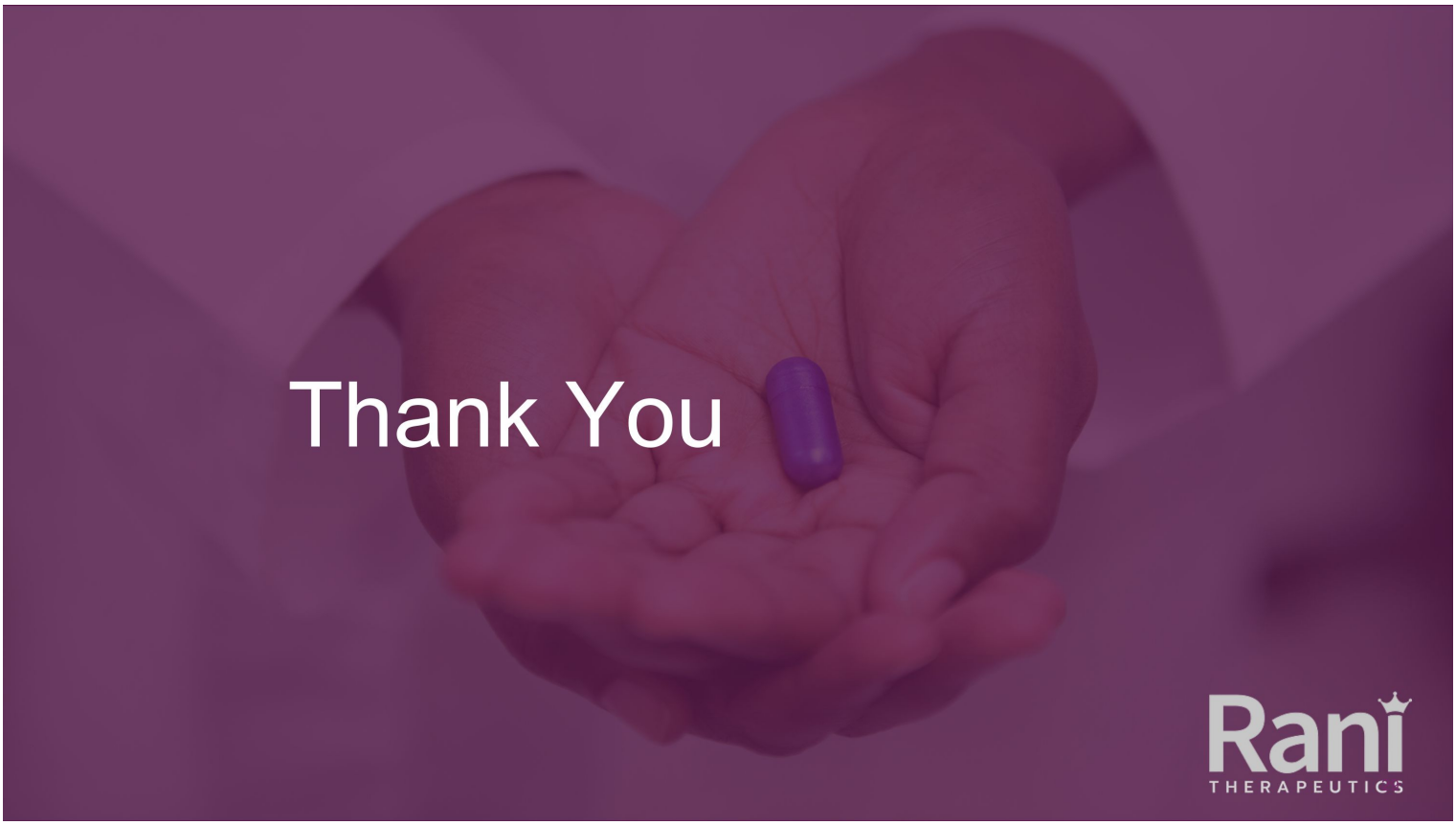
Goals

More convenient than small molecule

Equal or **better efficacy** compared to injectables

Potentially **lower AEs** than injectable biologics & small molecule

Rani THERAPEUTICS


Thank You
Rani
THERAPEUTICS

Additional Updates

Transenteric Delivery of GLP-1/GIP/Glucagon Molecule Elicits Rapid Weight Loss in Beagle Dogs

Objective

- To evaluate the PK-PD profiles of Blinded 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

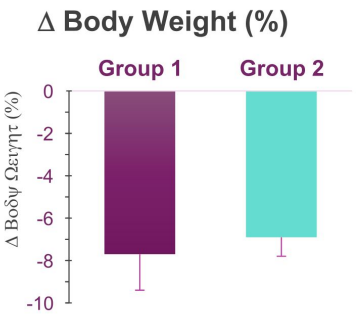
- Beagles, adult male, 11 - 13 kg, Total N=10

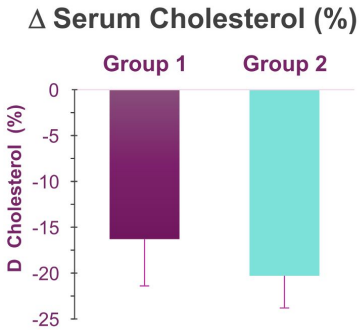
Test Groups

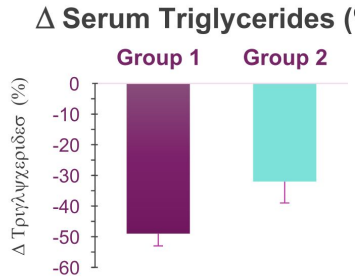
- Group 1 Transenteric (N=5): Triagonist, 0.12mg/kg (0.05ml/kg) injected via endoscopic access
- Group 2 SC (N=5): Triagonist, 0.12mg/kg (0.04ml/kg) injected subcutaneously

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







Group 1: Endoscopic
Group 2: SC

All data are Means ± SE

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	Daily or 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 [5]

Appendix

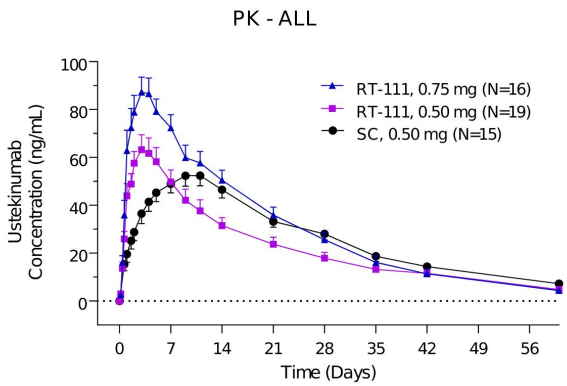
RT-111 Phase 1 Additional Data

Study Demographics – RT-111 Phase 1 Study

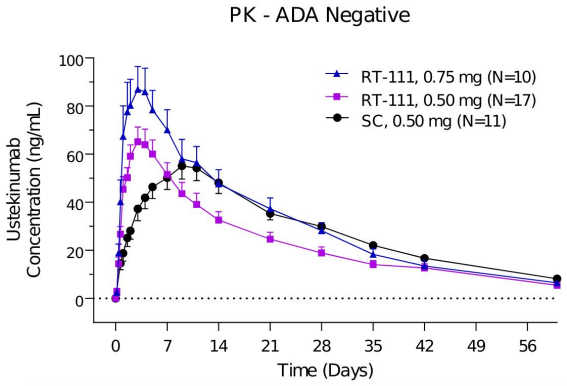
	SC 0.50 mg	RT-111 0.50 mg	RT-111 0.75 mg
N	15	20	20
Mean Age, years	**29.3 (19 - 49)**	**28.3 (20 - 39)**	**30 (20 - 58)**
Race			
Hispanic	0% (0/15)	25% (5/20)	5% (1/20)
White-non-Hispanic	60% (9/15)	35% (7/20)	75% (15/20)
Asian	40% (6/15)	35% (7/20)	20% (4/20)
Body Mass Index (kg/m^2)	23.8 ± 3.4	25.5 ± 3.7	22.9 ± 2.2
Height (cm)	172.7 ± 9.8	172 ± 9.7	170.2 ± 8.7
Weight (kg)	71.1 ± 12.7	76 ± 16.5	66.5 ± 9.5

BMI, Height and Weight data are Mean ± SD

PK Profiles of Oral Ustekinumab Biosimilar (RT-111) vs SC Stelara Injection



	SC 0.50 mg	RT-111 0.50 mg	RT-111 0.75 mg
C_{max} (ng/ml)	56 ± 4	67 ± 7	92 ± 8
T_{max} (days)	10 ± 0.8	3.1 ± 0.2	3.3 ± 0.2
AUC (day*ng/mL)	1,566 ± 130	1,315 ± 150	1,814 ± 165



	SC 0.50 mg	RT-111 0.50 mg	RT-111 0.75 mg
C_{max} (ng/ml)	58 ± 6	67 ± 7	93 ± 12
T_{max} (days)	10.2 ± 0.9	3.2 ± 0.2	3.1 ± 0.4
AUC (day*ng/mL)	1,678 ± 112	1,365 ± 142	1,883 ± 162

Rani THERAPEUTICS

Data are Means ± SEM. Data are pending final QA review.

References

(1) Data of third party molecules are from separate studies published or disclosed by such third parties. Data are not from head-to-head studies. For Humira data and PASI 75 at 16 weeks, see tables 17-18 in U.S. prescribing information. For Humira PASI 75 at 48 weeks, see Table 3 of EMA Summary of Product Characteristics for Tremfya 100mg pre-filled pen and 100mg pre-filled syringe .For Humira revenues and Skyrizi revenues, see AbbVie press release dated February 9, 2023 (AbbVie Reports Full-Year and Fourth-Quarter 2022 Financial Results).For Cosentyx data and PASI 75 at 12 weeks, see U.S. prescribing information and for PASI 75 at 52 weeks for 300mg dose, see Table 4 in EMA Summary of Product Characteristics for Cosentyx 75mg.For Cosentyx revenues, see Novartis In Society Integrated Report 2022, Financial Performance..For Taltz data and PASI 75 data at 12 weeks, see U.S. prescribing information. For Taltz PASI 75 at 60 weeks, see Table 5 of EMA Summary of Product Characteristics for Taltz 80mg pre-filled syringe For Taltz revenues, see Lilly press release dated February 2, 2023 (Lilly Reports Fourth-Quarter 2022 Financial Results, Core Business Growth and Pipeline Advancements Support Strong Long-Term Outlook).For Skyrizi data , see U.S. prescribing information. For Skyrizi PASI 75 at 12 weeks and 52 weeks, see Table 2 of EMA Summary of Product Characteristics for Skyrizi 150 mg pre-filled pen, and 75mg and 150mg pre-filled syringes. For Tremfya data and PASI 75 data at 16 weeks, see U.S. prescribing information. For Tremfya PASI 75 at 48 weeks, see Table 3 of EMA Summary of Product Characteristics for Tremfya 100mg pre-filled pen and 100mg pre-filled syringe. For Tremfya revenues, see DrugAnalyst market research database. For Stelara data and PASI 75 at 12 weeks, see U.S. prescribing information. For Stelara PASI 75 at 52 weeks, see EMA Summary Product Characteristics for Stelara 45mg and 90mg pre-filled pens. For Stelara revenues, see J&J annual earnings report for 2022.

(2) Data of third party molecules are from separate studies published or disclosed by such third parties. Data are not from head-to-head studies. For Otezla PASI data, see *Apremilast, an oral phosphodiesterase 4 (PDE4) inhibitor, in patients with moderate to severe plaque psoriasis: Results of a phase III, randomized, controlled trial (Efficacy and Safety Trial Evaluating the Effects of Apremilast in Psoriasis [ESTEEM] 1)*Papp et al, Journal of the American Academy of Dermatology,Volume 73, Issue 1, P37-49, July 2015. For Otezla revenue, see Amgen press release dated January 31, 2023 (Amgen Reports Fourth Quarter and Full Year 2022 Financial Results). For Otezla pill number, see Otezla U.S. prescribing information. For Sotyktu PASI data, see Bristol Myers Squibb press release dated October 11, 2023 (Sotyktu (deucravacitinib) Long-Term Data Demonstrate Durable Efficacy and Consistent Safety for up to Three Years in Moderate-to-Severe Plaque Psoriasis. For Sotyktu revenue, see Bristol Myers Squibb quarterly earnings press releases dated April 27, 2023, July 27, 2023, and October 26, 2023. For Sotyktu pill number, see Sotyktu U.S. prescribing information. For JNJ-2113 (PTG-200), PASI 75 scores are for 100mg dose (daily and twice daily); see Johnson & Johnson press release dated July 4, 2023 (Janssen Announces Positive Topline Results for JNJ-2113 - a Novel, First and Only Oral IL-23 Receptor Antagonist Peptide in Development for Moderate-to-Severe Plaque Psoriasis).

(3) Johnson & Johnson 2022 Annual Report.

(4) Abbvie 2022 Annual Report.

(5) Data of third party molecules are from separate studies published or disclosed by such third parties. Data are not from head-to-head studies. For Wegovy, seeprescribing information. For Mounjaro, see prescribing information and press release *Lilly's tirzepatide delivered up to 22.5% weight loss in adults with obesity or overweight in SURMOUNT-1,* Eli Lilly and Company, April 28, 2022. For oral semaglutide, The Lancet, *Oral semaglutide 50 mg taken once per day in adults with overweight or obesity (OASIS 1): a randomized, double-blind, placebo-controlled, phase 3 trial*, Knop et al, June 26, 2023, Doi.org/10.1016/ S0140-6736(23)01185-6. For retatrutide, (dosing and weight loss) press release, Lilly's phase 2 retatrutide results published in The New England Journal of Medicine show the investigational molecule achieved up to 17.5% mean weight reduction at 24 weeks in adults with obesity and overweight, Eli Lilly & Company, June 26, 2023. (Discontinuation) New England Journal of Medicine, *Triple-Hormone-Receptor Agonist Retatrutide for Obesity - A Phase 2 Trial*, Jastreboff et al, June 26, 2023, DOI: 10.1056/NEJMoa2301972. For orfoglipron, (Dosing and weight loss) New England Journal of Medicine, 389:877-888, DOI: 10.1056/NEJMoa2302392, September 7, 2023. (Discontinuation) New England Journal of Medicine, *Daily Oral GLP-1 Receptor Agonist Orforglipron for Adults with Obesity*, Wharton et al, June 23, 2023, DOI: 10.1056/NEJMoa2302392. For danuglipron, (discontinuation rate) Everyday Health, *Could This Pill Be the Next Ozempic?*, Ross Wollen, May 22, 2023. (Dosing) JAMA Network Open 2023;6(5):e2314493. Doi:10.1001/jamanetworkopen.2023.14493.