

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 23, 2022

Rani Therapeutics Holdings, Inc.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-40672  
(Commission  
File Number)

86-3114789  
(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 2.02 Results of Operations and Financial Condition**

On February 23, 2022, Rani Therapeutics Holdings, Inc. (the “Company”) issued a press release to announce the development of a high capacity RaniPill™ device and the outcome of an initial preclinical study related to the device, as well as to report preliminary consolidated financial results for the fourth quarter and year ended December 31, 2021. A copy of such press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference. The preliminary unaudited financial results contained in the press release do not present all information for an understanding of the Company’s financial condition as of December 31, 2021 and its results of operations for the quarter and year ended December 31, 2021. The audit of the Company’s financial statements for the year ended December 31, 2021 could result in changes to the information in the press release.

The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 to this Current Report shall be deemed to be “furnished” and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 to this Current Report shall not be incorporated by reference into any filing made by the Company with the U.S. Securities and Exchange Commission (the “SEC”) under the Securities Act or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 7.01 Regulation FD Disclosure.**

On and after February 23, 2022, the Company will participate in conferences with investors and analysts. A copy of the Company’s presentation has been posted to the Company’s website and is attached hereto as Exhibit 99.2.

The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 and Exhibit 99.2 to this Current Report shall be deemed to be “furnished” and shall not be deemed to be “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act. The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 and Exhibit 99.2 to this Current Report shall not be incorporated by reference into any filing made by the Company with the SEC under the Securities Act or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

Exhibit No.	Description
99.1	<a href="#">Press Release of Rani Therapeutics Holdings, Inc. dated February 23, 2022</a>
99.2	<a href="#">Presentation dated February 2022</a>
104	Cover page interactive data file (embedded within the iXBRL 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: February 23, 2022

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



**Rani Therapeutics Unveils High-Capacity RaniPill™ Device For  
Oral Delivery of Biologics; Reports Preliminary 2021  
Consolidated Financial Results**

- *Preclinical data demonstrates new RaniPill™ HC (High Capacity) delivered 500%-plus higher payloads than current RaniPill™ capsule -*
- *Up to 20mg payload has the potential to unlock more than 50 additional biologics for internal development or partnership -*
- *Company announces preliminary consolidated financial results for the fourth quarter and year ended December 31, 2021 -*

**SAN JOSE, Calif., Feb. 23, 2022** — Rani Therapeutics Holdings, Inc. (“Rani Therapeutics” or “Rani”) (Nasdaq: RANI), a clinical-stage biotherapeutics company focused on the oral delivery of biologics, today announced the development of a high-capacity oral biologics device known as the RaniPill™ HC (High Capacity), capable of delivering up to a 500%-plus higher drug payload than Rani’s existing oral biologics capsule. In preclinical testing, RaniPill™ HC demonstrated successful delivery of adalimumab and achieved high bioavailability.

“The RaniPill™ HC gives us the potential to deliver a much broader range of biologic drugs with its higher capacity of up to 20mg of drug per capsule,” said Mir Imran, Rani’s founder and Executive Chairman. “In addition, since the RaniPill™ HC shares many similarities with our existing RaniPill™ capsule, we are confident in our ability to achieve similar safety and performance metrics, and to leverage our existing investments in manufacturing and automation.”

Today, biologics are predominantly delivered via injection or intravenous infusion, which limits long-term treatment adherence, often leading to suboptimal patient outcomes. An equally effective oral alternative could change the treatment paradigm for a number of patient populations, including those with autoimmune diseases, cancer, and diabetes.

“Therapeutic drug development has yielded a vast array of molecular entities, including peptides, antibodies and oligonucleotides. The new technology from Rani now allows for the potential oral administration of these drugs irrespective of their size or chemical nature,” said Dr. Dennis Ausiello, a member of Rani’s Board of Directors. Dr. Ausiello is the Director of the Center for Assessment Technology & Continuous Health (CATCH) and was previously Chief of Medicine at Massachusetts General Hospital.

Rani conducted a preclinical study of RaniPill™ HC, with each device containing an 18mg dose of the biologic adalimumab, a tumor necrosis factor (TNF)-α inhibitor that is approved for multiple autoimmune conditions including rheumatoid arthritis and Crohn’s disease. The unencapsulated RaniPill™ HC device was placed laparoscopically in the jejunum of each of three canine test subjects and allowed to self-deploy under observation. Successful delivery was achieved in all cases, and systemic serum drug concentration was detected and measured over 5 days. A copy of the data is available on the Presentations page of Rani Therapeutics’ investor relations website: <https://ir.ranitherapeutics.com/news-events/presentations>.

“The RaniPill™ HC is a major milestone for our platform technology. It opens up a significant number of opportunities for new pipeline drugs and partnerships,” said Talat Imran, Rani’s CEO. “This sets the stage for the rest of the year, as we anticipate moving two programs into the clinic using our existing RaniPill™ capsule, while also advancing development of the RaniPill™ HC for high-dose biologics. We believe these technologies have the potential to improve the lives of millions of patients with chronic diseases who currently depend on frequent injections.”

#### **Preliminary Consolidated Financial Results**

Rani’s preliminary consolidated financial results for the three months and year ended December 31, 2021 are presented below, and the results are subject to finalization of the Company’s customary quarterly and annual financial close processes.

- Rani estimates that net loss will be between \$13.0 million and \$15.0 million for the fourth quarter of 2021, compared to \$5.8 million for the fourth quarter of 2020, and between \$53.0 million and \$55.0 million for the full-year 2021, compared to \$16.7 million for full-year 2020. The net loss includes estimated equity-based compensation expense of approximately \$3.2 million for the fourth quarter of 2021 and approximately \$22.6 million for the full-year 2021. There was no equity-based compensation expense for the fourth quarter of 2020 nor full year-year 2020.
- Rani estimates that cash and cash equivalents will be approximately \$117.5 million as of December 31, 2021.

#### **Information Regarding Preliminary Results**

The estimate of net loss and our cash and cash equivalents is preliminary and subject to completion, including the completion of audit procedures as of and for the year ended December 31, 2021. As a result, the unaudited preliminary net loss and cash and cash equivalents set forth above reflect our preliminary estimate with respect to such information, based on information currently available to management, and may vary from our actual consolidated financial position as of December 31, 2021. Further, this preliminary estimate is not a comprehensive statement or estimate of our consolidated financial results or financial condition as of and for the year ended December 31, 2021. Ernst & Young LLP, our independent registered public accounting firm, has not audited, reviewed, compiled, or performed any procedures with respect to the unaudited preliminary net loss or cash and cash equivalents. Accordingly, Ernst & Young LLP does not express an opinion or any other form of assurance with respect to the unaudited preliminary net loss and cash and cash equivalents. It is possible that we or Ernst & Young LLP may identify items that require us to make adjustments to the consolidated financial information. The information presented above should not be considered a substitute for the consolidated financial information to be filed with the Securities and Exchange Commission in our Annual Report on Form 10-K for the year ended December 31, 2021 once it becomes available and should not be regarded as a representation by us or our management as to our actual financial results for the three months or year ended December 31, 2021. The ranges for the preliminary estimated consolidated financial results described above constitute forward-looking statements, are subject to change, and our actual financial results may differ from such preliminary estimates and such differences could be material. Accordingly, you should not place undue reliance upon these preliminary estimates.

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**Rani Therapeutics**

Rani Therapeutics is a clinical stage biotherapeutics company focused on advancing technologies to enable the development of orally administered biologics. Rani has developed the RaniPill™ capsules, which are a novel, proprietary and patented platform technology, intended to replace subcutaneous injection or intravenous infusion of biologics with oral dosing. Rani has successfully conducted several preclinical and clinical studies to evaluate safety, tolerability and bioavailability using RaniPill™ capsules. For more information, visit [ranitherapeutics.com](http://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, Rani’s preliminary consolidated financial results, Rani’s development and advancement of its RaniPill™ capsule technology, including RaniPill™ HC, the impact of its technology on medical treatment, Rani’s advancement of its preclinical and clinical programs, customer acceptance of the RaniPill™ capsule technology, the potential benefits of the RaniPill™ capsule technology, Rani’s prospects for entering into strategic partnerships or transactions, and Rani’s growth as a company. 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 “may,” “could,” “anticipate,” “believe,” “look forward,” “progress,” “advance,” “potential”, “be able to” 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, the impact of the COVID-19 pandemic, and the other risks described in Rani’s filings with the Securities and Exchange Commission. 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:**

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**Media Contact:**

media@ranitherapeutics.com

# Rani Therapeutics

Announcing RaniPill™ HC



February 2022

**Rani**  
THERAPEUTICS

# Forward Looking Statements

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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, market potential of our products, and our ability to achieve and maintain future profitability, those risks inherent in product development and 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 develop, optimize and scale manufacturing processes, the extent and duration of the COVID-19 pandemic, our expectations regarding customer demand for our product candidates, our ability to expand the potential market for our products 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 may 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.

This presentation and the accompanying oral presentation 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.

# Rani Platforms & Payloads

DEVICE	CAPACITY	POTENTIAL # OF DRUGS ENABLED	SELECT POTENTIAL DRUGS
Current RaniPill™ capsule	Up to 3 mg	>40	<ul style="list-style-type: none"><li>• Octreotide</li><li>• Parathyroid hormone for osteoporosis</li><li>• Parathyroid hormone for hypo</li><li>• Human growth hormone</li><li>• Anti TNF-α antibody</li></ul>
RaniPill™ HC (High-Capacity)	Up to 20 mg	>50	<ul style="list-style-type: none"><li>• Pembrolizumab / Keytruda®</li><li>• Etanercept / Enbrel®</li><li>• Trastuzumab / Herceptin®</li><li>• Secukinumab / Cosentyx®</li></ul>

The high payload RaniPill™ HC will enable the potential delivery of a wider variety of drugs and may **significantly expand our market opportunity**



## RaniPill™ HC Study

# High Payload System: Study Objectives

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- Demonstrate ability to deliver high drug payloads (up to 20 mg) in canines
- Verify that the absorption profile of adalimumab delivered via the RaniPill™ HC device is consistent with previously established historical controls with an adalimumab biosimilar

# RaniPill™ HC – Adalimumab: Protocol Summary

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- Test Device
  - RaniPill™ HC device without enteric-coated capsule shell or chemical reactants
- Test Article & Dose
  - Adalimumab: 18 mg / 20 mg
- Protocol
  - RaniPill™ HC device inserted directly into the jejunum lumen via a laparotomy
  - The RaniPill™ balloon was inflated by an external syringe pump (actuation pressure similar to existing RaniPill™ device)
  - Incisions closed with sutures
- Blood Sample Collection
  - 3 mL blood samples collected at the following time points:  
0 (pre-dose), 4-hr, 8-hr, 12-hr, 24-hr, 2-day, 3-day, 4-day, and 5-day

# Study Animal Details

Animal ID	Animal #5074	Animal #5077	Animal #5080	Animal #5042	Animal #5084
Species:	Canine	Canine	Canine	Canine	Canine
Sex:	Male	Male	Female	Male	Female
Weight:	13.1 kg	14.2 kg	11.6 kg	16.7 kg	11.8 kg
Adalimumab Dose:	18 mg	18 mg	18 mg	20 mg	20 mg
Route of Admin:	RaniPill™ HC	RaniPill™ HC	RaniPill™ HC	SC	SC

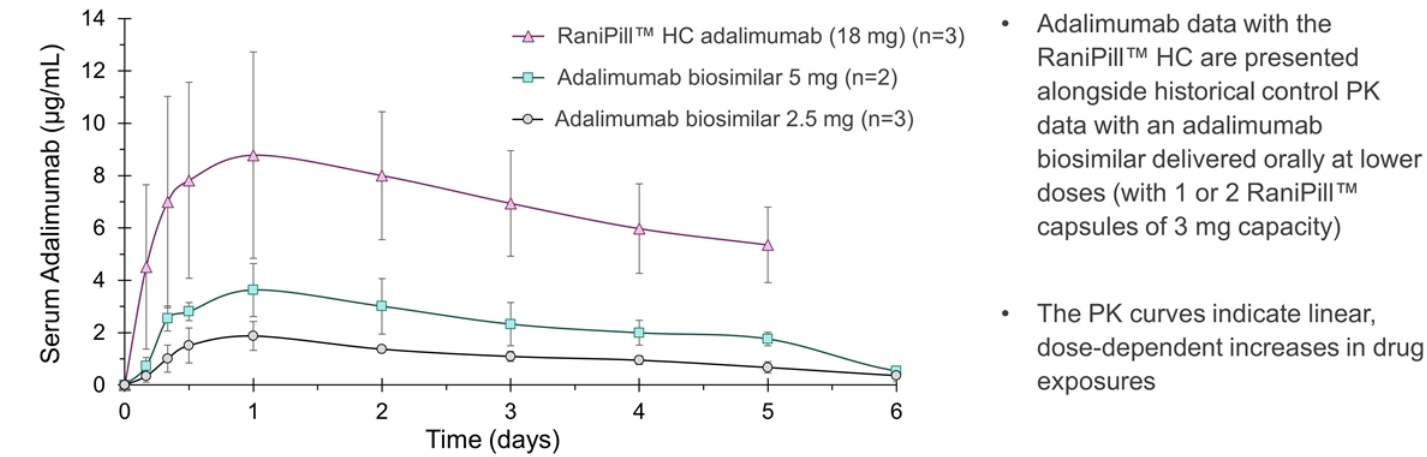


SC = Subcutaneous

# Pharmacokinetics (PK) of Adalimumab ~18 mg Delivered via the RaniPill™ HC

## PK Curves of an Adalimumab Biosimilar (~2.5 mg and 5 mg, Historical Data) delivered via the RaniPill™ Capsule in Awake Canines vs Adalimumab ~18 mg delivered via RaniPill™ HC

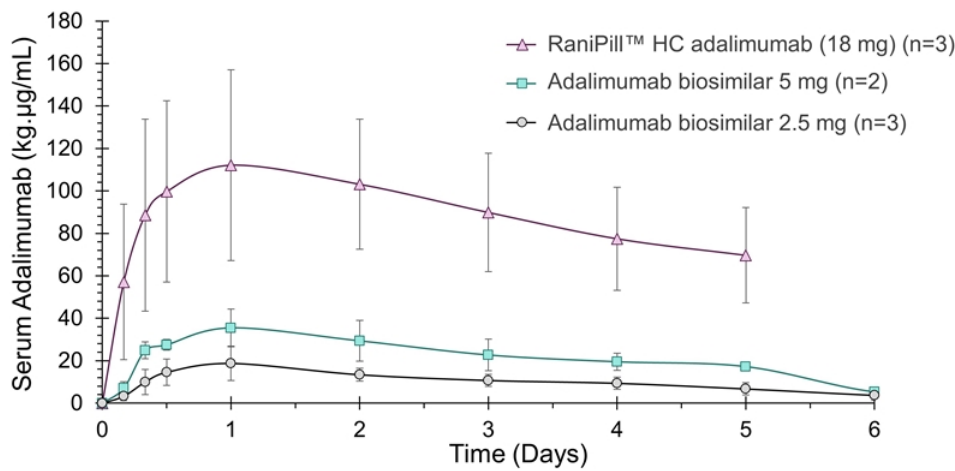
All data are means ± Standard Deviation (SD)



# PK of Adalimumab ~18 mg Delivered via the RaniPill™ HC

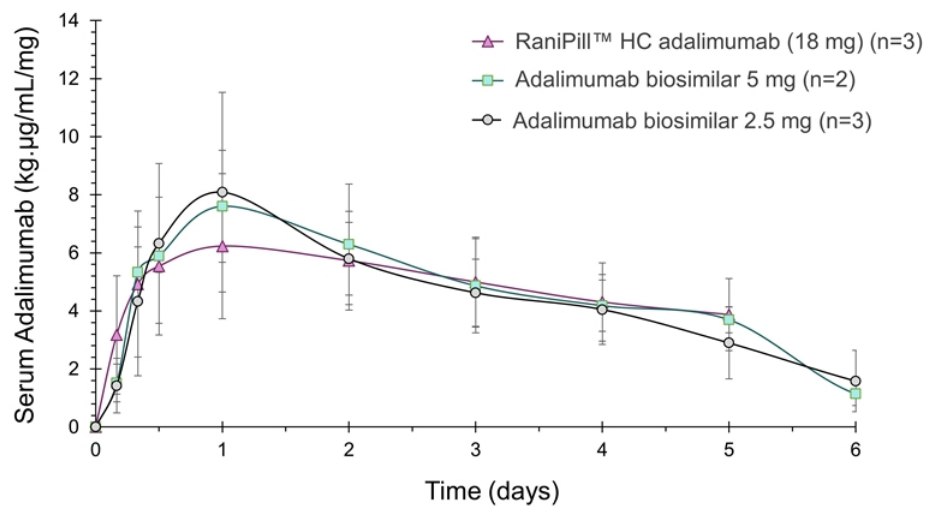
Weight-Normalized PK Curves of an Adalimumab Biosimilar (~2.5 mg and 5 mg, Historical Data) delivered via the RaniPill™ Capsule in Awake Canines vs Adalimumab ~18 mg delivered via RaniPill™ HC

All data are weight-normalized means ± Standard Deviation



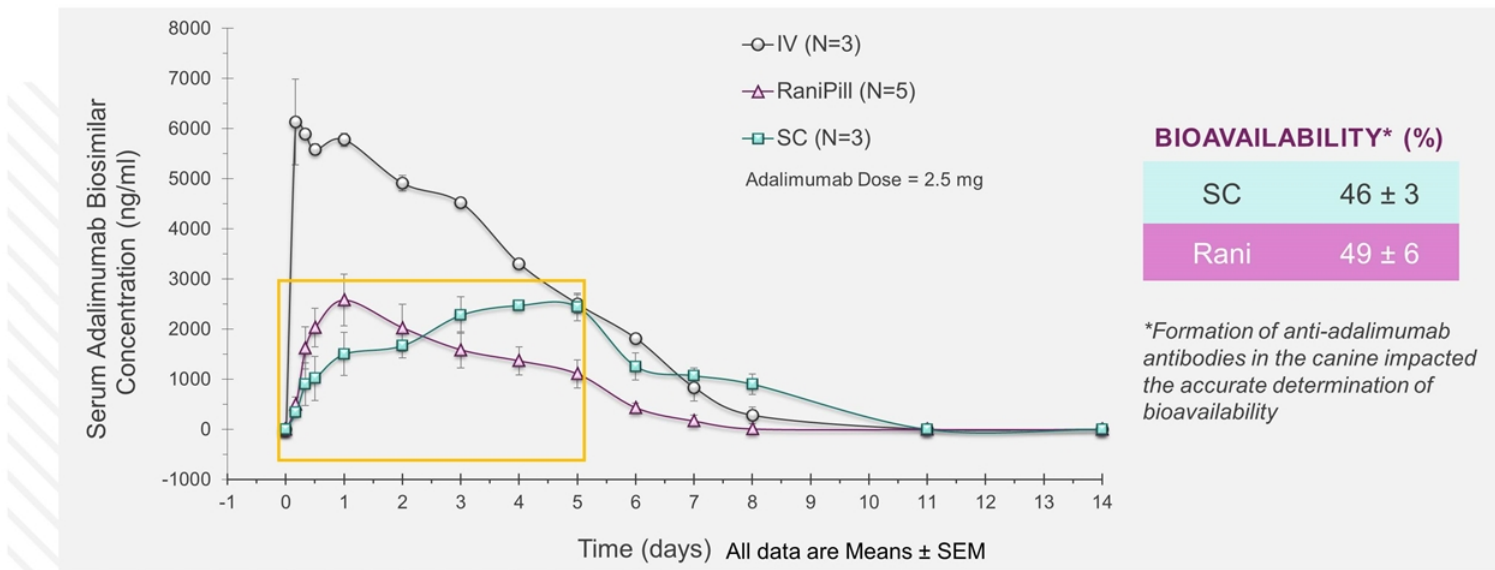
# Adalimumab PK Profiles Delivered via the RaniPill Route

**Dose- and Weight-Normalized PK Curves of an Adalimumab Biosimilar (2.5 mg and 5 mg, Historical Data) delivered via the RaniPill™ capsule vs. Adalimumab ~18 mg delivered via RaniPill™ HC**



- The PK curve of adalimumab generated with the RaniPill™ HC device is similar to historical PK curves generated with an adalimumab biosimilar delivered via 3 mg RaniPill™ capsules
- Note that elimination phase of RaniPill™ HC was not fully captured as data were collected for only up to 5 days in this initial study

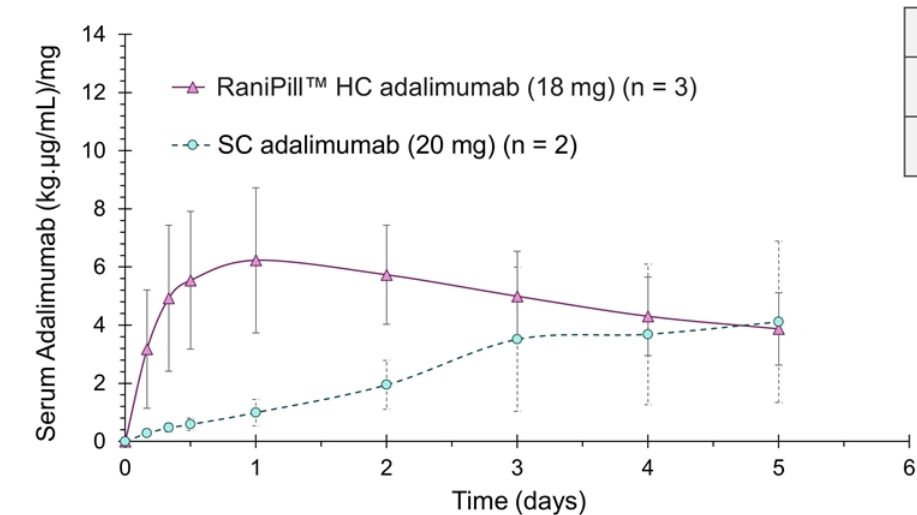
# Historical PK of Oral Adalimumab Biosimilar in Awake Canines



IV = Intravenous  
Rani or RaniPill = RaniPill capsule  
SC = Subcutaneous

# PK Comparison: RaniPill™ HC vs Subcutaneous (SC) Controls

All data are weight- & dose-normalized means ± SD



	RaniPill™ HC (n = 3)	SC (n = 2)
C <sub>max</sub> (kg.µg/mL)/mg	6.4 (3.81, 7.24, 8.06)	4.1 (2.15, 6.07)
T <sub>max</sub> (hours)	32 (48, 24, 24)	120 (120, 120)

- The shorter T<sub>max</sub> and higher C<sub>max</sub> seen with the RaniPill™ HC-adalimumab are consistent with historical data with an adalimumab biosimilar delivered via 3 mg RaniPill™ capsules
  - Recall that in our studies the absolute bioavailability (%F) of adalimumab delivered via the RaniPill™ route is on par with SC injections
- Note that elimination phase was not fully captured as data were collected for only up to 5 days in this initial study

## Summary









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- Using the RaniPill™ HC device, we have demonstrated successful delivery of a high dose (18 mg) of adalimumab in canines
- Adalimumab 18 mg administered by the RaniPill™ HC device showed a dose-proportional increase in serum concentrations in comparison to historical controls with an adalimumab biosimilar (delivered via current RaniPill™ capsule) at lower doses (2.5 mg and 5 mg)
  - Tmax of adalimumab was shorter with the RaniPill™ HC device compared to SC controls
  - Data are consistent with Rani historical controls with an adalimumab biosimilar



## Market Research

## Patient Preference Surveys\*

								
Frequency	Daily	Every 2 weeks	Every 2 weeks	Every month	Every month	Every month	Every 12 weeks	Every 6 months
% Likely to Switch to Daily Pill Over Current Injectable	87%	88%	77%	74%	73%	75%	64%	76%

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

\*Data for Lantus and Humira obtained from an independent third-party survey commissioned by Rani in 2017 to investigate U.S. patient preference for a daily oral alternative. Patients surveyed were aged 18 years or older. Two patient groups included 501 patients taking Humira for the treatment of an inflammatory condition and 577 patients taking basal insulin for the treatment of diabetes.

# Mock-RaniPill™ Swallow Study Overview

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- **Objective:** To evaluate the ease of swallowability of a mock RaniPill™ capsule by patients of different ages
- **Patient Population:** Patients currently taking injections of various drugs
- **Study Design**
  - Three cohorts of patient age groups: 21-50, 51-65, 66-75 years
  - N = 50 in each group
- **Test Article:** An enteric coated mock RaniPill™ capsule (of same weight and size as current RaniPill™ capsule) filled with potato starch
- **Endpoints**
  - Swallowability and palatability of the mock RaniPill™ capsule
  - Participants' preference to choose a pill instead of their current injection therapy
- Study initiated in June 2021 and completed in September 2021

# Swallow Study Results

Study Groups (years)	# Total Enrolled	# successfully swallowed Mock-RP	# Prefer Pill over Injection	% Prefer Pill over Injection	# Prefer Injection over Pill
21-50	50	50	44	88%	6
51-65	50	50	48	96%	2
66-75	50	50	44	88%	6
Total	150	150	136	91%	14



## Adalimumab: Simulations of Daily Oral RaniPill Dosing

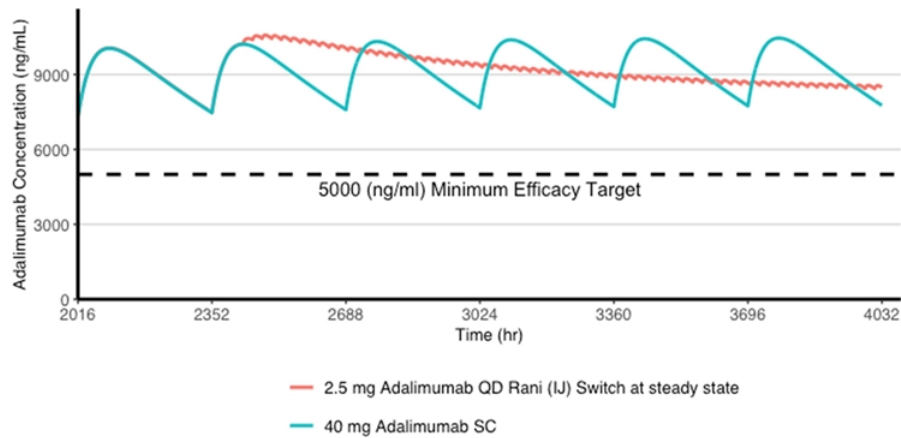
# The Power of Daily Dosing

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- Adalimumab is dosed at 40 mg every 2 weeks, which we hypothesized would be approximately equivalent to a ~2.5 mg daily dose
- Using the data from our human endoscopic study (2.5 mg of adalimumab injected intra-jejunally), we commissioned steady-state simulations to model the pharmacokinetics of a once daily oral RaniPill dose of 2.5 mg adalimumab
- Based on the simulations, it is projected that:
  - Therapeutic levels of serum adalimumab can be achieved with a once daily oral RaniPill dose of 2.5 mg
  - Loading doses (i.e., 40 mg subcutaneous dose or 2 weeks of twice daily oral dosing) reduce the amount of time to reach therapeutic levels
  - Patients currently on adalimumab 40 mg biweekly dosing regimen can switch to the daily RaniPill regimen at any point following the last SC dose of adalimumab

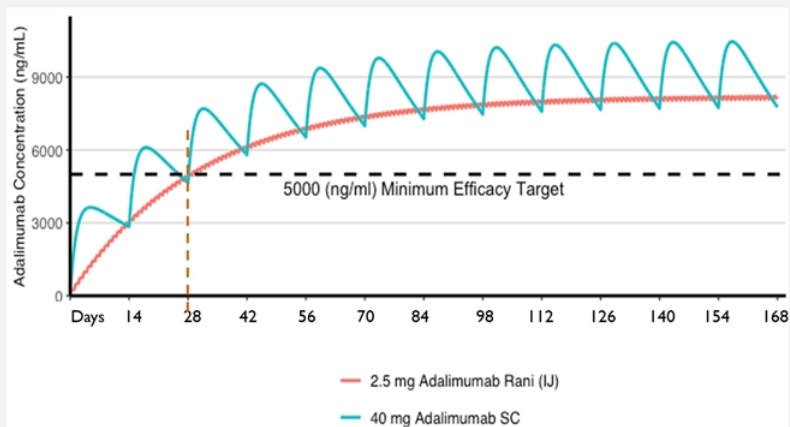
Steady State PK Simulations of Adalimumab Intrahepatal (IJ) Data: Switching from Subcutaneous

*It is projected that patients currently on adalimumab 40 mg biweekly dosing regimen could switch to the daily RaniPill™ regimen at any point following the last subcutaneous dose of adalimumab*



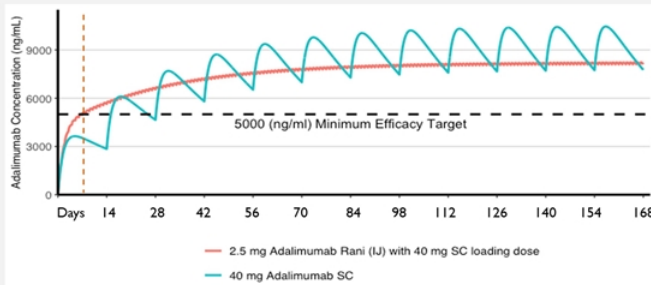
## Steady State PK Simulations of Adalimumab IJ Data: Daily Dosing

RT-105  
Regimen: daily dosing of 2.5 mg RaniPill™  
capsule, no loading dose

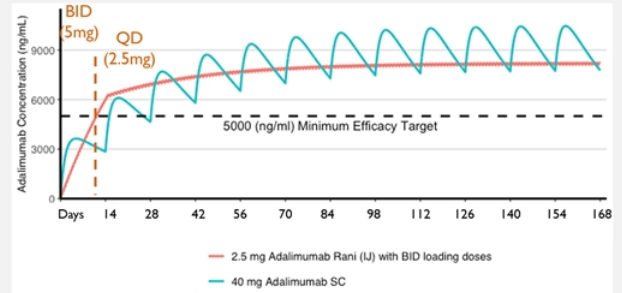


- With biweekly adalimumab SC injections at a dose of 40 mg, it takes 28 days to reach target efficacy steady states
- With once daily oral RaniPill™ dose of 2.5 mg, it is projected to take ~28 days to reach target efficacy steady state

# Steady State PK Simulations of Adalimumab IJ Data: Loading Doses





- Starting with an initial 40 mg SC loading dose, it is projected to take 7 days to reach target efficacy steady state with the 2.5 mg RaniPill™ capsule



- With initial 2 week BID (twice daily) RaniPill™ capsule loading doses, it is projected to take ~10 days to reach target efficacy steady state
  - After 2 weeks of BID dosing, the patient would switch to QD (daily) maintenance dose with a single RaniPill™ capsule

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

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

Thank you!

