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Rani Therapeutics Holdings, Inc. (RANI: NASDAQ)

RANI: 2023 Results

Rani's valuation relies on a DCF model and a 15% discount rate applied to our cash flow estimates. We apply a success probability of 30% to RT-102, 30% to RT-111 and 25% to RT-105. The model includes contributions from the United States and rest of world.

Current Price (3/20/2024)	$3.57
Valuation	**$12.00**

OUTLOOK

Rani is a clinical-stage biotherapeutics company developing the ingestible robotic RaniPill (RP) that enables oral delivery of biologics & other large molecules. Its pipeline features clinical assets RT-102 (teriparatide for osteoporosis) & RT-111 (ustekinumab for psoriasis). Both programs have completed Ph1 trials characterizing safety tolerability & pharmaco-kinetics. Adalimumab for psoriasis (RT-105) & teriparatide for hypo-parathyroidism (RT-110) are in preclinical development.

Other Rani initiatives include development of larger capacity pills & collaborations with biopharmaceutical companies. Next steps include the start of Phase II for RT-102 and a combined dose finding/Phase II for RT-111.

RP expands delivery options for biologics that now require parenteral administration. An oral option would provide product life cycle management, improved comfort of administration, greater compliance and im-proved dosing regimens which would improve efficacy and reduce side effects.

We expect clinical trials will be completed and approval granted for RT-102 and RT-111 in 2027. If RP proves successful in delivering biologics for these initial indications, we see material penetration opportunity into the $300B+ biologics market which offers few oral alternatives.

SUMMARY DATA

52-Week High	**6.12**
52-Week Low	**1.82**
One-Year Return (%)	**-43.6**
Beta	**1.0**
Average Daily Volume (sh)	**78,586**
Shares Outstanding (mil)	**51.3**
Market Capitalization ($mil)	**177.0**
Short Interest Ratio (days)	**23.3**
Institutional Ownership (%)	**13.5**
Insider Ownership (%)	**48.7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2024					$0.0 E
2025					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2022	-$0.29 A	-$0.31 A	-$0.33 A	-$0.36 A	-$1.28 A
2023	-$0.33 A	-$0.37 A	-$0.36 A	-$0.27 A	-$1.33 A
2024					-$1.00 E
2025					-$0.82 E

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WHAT'S NEW

Rani Therapeutics Holdings, Inc. (NASDAQ: RANI) began 2024 with topline results from its Phase I study of RT-111, or ustekinumab, delivering the biologic with its ingestible robotic RaniPill (RP). Bioavailability of 84% relative to subcutaneous injection was achieved in the study and the RT-111 was well tolerated and no serious adverse events were observed in trial participants. This successful result follows supporting results from two other clinical trials that found the RP to be safe, tolerable and effective in drug delivery providing a firm foundation for further development of the device.

On March 20th, the company reported full year 2023 results producing a net loss of ($67.9) million and cash burn of $52.5 million. A shift in strategy announced last November narrowed Rani's focus to the RT-111, RT-102 and RP high capacity (HC) programs; a change which is expected to extend the company's cash runway. As we look forward to 2024, we expect to see a favorable response from Celltrion with respect to its right of first negotiation for the RT-111 program. If signed, an agreement with the Korean biologics developer may include upfront payments that will extend the company's runway even further.

Full Year 2023 Operational and Financial Results

Rani reported 2023 results in a press release and Form 10-K filing with the SEC on March 20, 2024. The company also held a conference call for analysts and investors following the reports. For the year ending December 31, 2023, revenues were zero matching prior year amounts. Operating expense was $66.1 million and net loss per share for Class B shareholders was ($1.33).

- Research and development expenses totaled $39.6 million, up 8.2% from $36.6 million due to higher third-party services expense related to preclinical and clinical development activities as well as greater facilities, materials and supplies costs;
- General & Administrative expenses were $26.5 million, falling 1.4% from $26.8 million on account of lower expenses related to third party services related to compliance with public company requirements and reduced facilities, material and supplies expense partially offset by higher compensation expense;
- Net interest and other expense totaled ($1.8) million compared to $177,000 on higher debt service costs;
- Non-controlling interest was ($33.9) million vs. ($32.8) million;
- Net loss for Class A shareholders was ($33.9) million vs. ($30.6) million or ($1.33) and ($1.28) per share, respectively.

As of December 31, 2023, cash totaled $48.5 million. This amount compares to the $98.5 million balance in cash held at the end of 2022. Long-term debt was held on the balance sheet at $29.4 million. 2023 cash used in operations was ($52.5) million versus ($48.1) million for the twelve months in 2022.

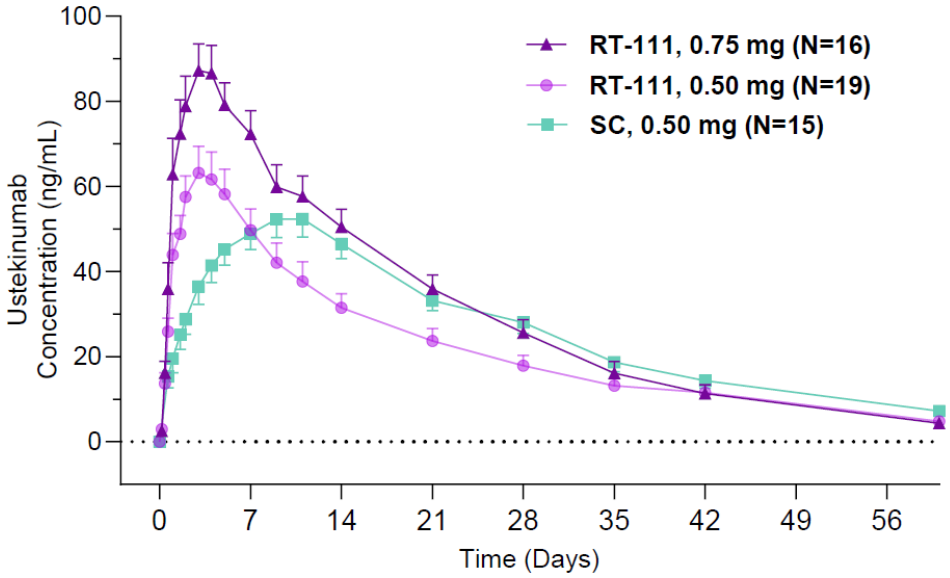
During the conference call, management noted that there sufficient cash and equivalents are available to fund operations into 2025 but that the company would need additional capital. Rani's CFO specified sources from equity, debt and licensing agreements from pharmaceutical partners as most likely. The company may tap into the remaining $15 million on a loan agreement if certain milestones are met and is party to a controlled equity sales agreement which allows the company to conduct at the market (ATM) equity sales.

RT-111 Phase I Study Results

Rani shared topline results from its Phase I study for RT-111 in a press release and webcast on February 5, 2024. RP achieved 84% bioavailability for the RP relative to subcutaneously delivered Stelara. RT-111 was well tolerated with no serious adverse events (AEs). Data from the study has now been passed on to partner Celltrion who has the right of first negotiation for worldwide rights to the product. While not explicitly stated, we surmise that Celltrion has accepted its right to negotiate and the two parties are now in the throes of negotiations.

The Phase I trial was designed to assess the safety, tolerability and pharmacokinetics of ustekinumab delivered using the RP. Fifty-five healthy volunteers in Australia were enrolled to participate in one of three study groups: a control group of 0.5 mg of Stelara (N=15), a 0.5 mg RT-111 group (N=20) or a 0.75 mg RT-111 group (N=20). Drug was administered after an overnight fast and blood samples were collected for the following 60 days to measure for serum ustekinumab concentration. Anti-drug antibodies were analyzed and excretion of the device was monitored.

Exhibit I – Pharmacokinetics of Ustekinumab[1]



One AE was observed in the Stelara arm and two AEs were observed in the 0.5 mg arm for RT-111. Drug related AEs included abdominal bloating and injection site rash. Potential RP-related AEs were a burning sensation in the stomach.

Rani plans to optimize the loading dose of RT-111 and maintain serum concentration levels within the optimal therapeutic range through more frequent dosing. RT-111's higher C_{MAX} and faster T_{MAX} will provide more flexibility in achieving better drug levels sooner. An oral option will allow for more dosing flexibility to help maintain blood concentration levels within the optimal therapeutic window of 0.7 µg/ml. Stelara has difficulty remaining in this window with recommended injections every 12 weeks which produce an initial spike followed by sub-therapeutic levels prior to the next administration. While additional studies will be required to find the correct dose and periodicity, improved outcomes are expected.[2]

The arrangement with Celltrion allows Rani's partner 30 days to decide whether or not to begin negotiations for a deal. Based on management comments, it appears that the negotiations are ongoing. Following Celltrion's entry into negotiations, the discussions between the two parties will be exclusive for 90 days during which time the parties may come to a definitive agreement for rights to develop and commercialize RT-111. If Celltrion passes on the deal or the time expires, Rani may negotiate with others.

If a deal is signed with Rani and Celltrion, we anticipate that the latter will assume the costs and primary management of further clinical trials and provide upfront payments to Rani. If another partner is not found, then we anticipate Rani will advance RT-111 into a Phase II which would encompass a dose finding element. However, the data from the trial presented last month was compelling and no other competing oral alternative comes close to providing the same level of bioavailability for biologics. Later development activities will require a supplemental BLA to be filed after a registrational study given ustekinumab's molecular profile.

RT-105 Development

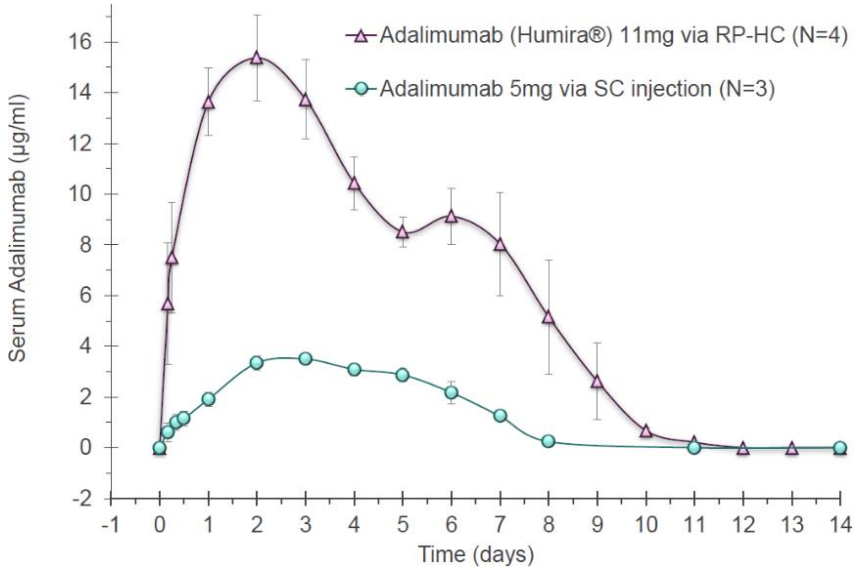
Rani is developing RT-105 for oral administration of an anti-TNF-alpha antibody for the treatment of a host of inflammatory conditions. Preclinical studies with adalimumab (Humira) and an adalimumab biosimilar in the canine model, with both RP GO and HC configurations, produced similar PK profiles and confirmed the bioavailability via the RP platform to be high and similar to SC injection.

One of Rani's studies in canines evaluated 11 mg of adalimumab in the RP HC, compared with 5 mg administered via SC injection. Shown below are the serum concentrations for both groups. Adalimumab administered orally via

[1] Rani Therapeutics Corporate Presentation. February 5, 2023.
[2] An earlier third-party study not affiliated with Rani demonstrated improved efficacy in psoriasis as shown in an improved PACI score for the 4x weekly 90 mg dose compared with the approved 45 mg dose. The proportion of AEs was lower in the 90 mg dose (68%) than it was for the 45 mg dose (90%) (See Table 3 in following reference link). Despite the better performance and lower AEs associated with the 90 mg dose, the sponsor may have elected to pursue the lower dose in order to reduce injection frequency. Krueger, G. *et al*. A Human Interleukin-12/23 Monoclonal Antibody for the Treatment of Psoriasis. The New England Journal of Medicine. February 2007.

RP HC produces higher bioavailability compared to SC administration. These data provide a successful demonstration of biologic delivery with high bioavailability enabled by the RP HC at a high dose, as high doses are needed for some indications of adalimumab such as Crohn's disease, ulcerative colitis and plaque psoriasis.

Exhibit II – Serum Concentration of Adalimumab for RaniPill HC and Subcutaneous Injection[3]



Milestones

- Feedback from pre-IND meeting for RT-102 – January 2023
- Celltrion partnership for RT-111 development (ustekinumab biosimilar) – January 2023
- Kate McKinley appointed Chief Business Officer – May 2023
- Celltrion partnership expansion for TR-105 (adalimumab) – June 2023
- RT-111 Phase I study initiated (ustekinumab) – September 2023
- Completion of GLP safety study – October 2023
- Strategic reorganization – November 2023
- Topline results for RT-111 Phase I study – February 2024
- Launch of RT-102 Phase II study – mid-2024
- RaniPill HC Phase I trial – 2H:24
- Partnership development – 2024

February 20th, 2024 Initiation

We initiated coverage of Rani Therapeutics last month with a target price of $12.00 per share. This value is based on our forecasts for the successful development and commercialization of the RaniPill (RP) technology platform for osteoporosis, psoriasis and psoriatic arthritis. The two clinical programs have completed Phase I studies and are continuing development with future regulatory milestones and anticipated submission to the FDA. The osteoporosis program, designated RT-102 is evaluating teriparatide delivery while the psoriasis program, designated RT-111, will assess delivery of an ustekinumab biosimilar. The adalimumab biosimilar program, RT-105, is in preclinical development. Rani's first approved program is expected to validate the technology platform, clearing the way for broader application of oral delivery for biologics. While there are a few approved methods of oral delivery of biologics, these approaches have limitations related to drug absorption. Biologics represent a $300 to $400 billion market for a class of drug with impressive efficacy but inconvenient administration. Biologics frequently require a trip to the clinic, administration by a provider, pain via injection and the risk of infection. The RP's ability to provide an effective method of oral administration for this class could sidestep these hurdles and dramatically improve convenience and compliance as well as improve efficacy for the fast-growing segment.

[3] Source: Rani Therapeutics December 2023 Corporate Presentation

The RP technology consists of a robotic pill that can deliver biologics orally. There are two configurations of the RP: RP GO and RP high capacity (HC). RP GO is designed to deliver a dissolvable microneedle containing a solid dose of approximately 3 mg of drug. RP HC is designed to deliver a liquid dose of 20 mg or more of drug. Each has a proprietary coating that protects the capsule in the stomach environment. In the higher pH of the small intestine, the coating dissolves, a balloon inflates to deliver the drug into the intestinal wall or surrounding tissue where it disperses systemically. The non-dissolvable remnants of the RP are excreted normally through the GI tract.

Exhibit III – Rani Therapeutic Pipeline[4]

	INDICATION(S)	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT EXPECTED MILESTONE*
RT-111	Psoriasis	Ustekinumab**				Advance Clinical Development at Higher Doses
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

Summary

Rani has made advances on a number of fronts including excellent bioavailability, tolerability and safety as reported in the topline for its RT-111 program last month. We surmise that Rani is negotiating with Celltrion regarding the next steps for the ustekinumab biosimilar. These results build on similarly supportive data from two other RP trials for RT-105 and RT-102. If Celltrion takes the baton from Rani for RT-111, we may see and upfront payment which can support the advancement of RT-102, RT-105 and/or a GLP-1 agonist candidate into the lead position. Each has a compelling argument in terms of convenience, market size, supportive data and substantial savings in terms of costs of goods sold for sponsors. We update our model to reflect data in the 2023 Form 10-K which yields an immaterial change ot our valuation. The valuation remains at $12.00 per share.

Key reasons to own Rani Therapeutics shares:

- **Offers oral delivery platform for biologics and large molecules**
  - **Provides improved convenience and compliance vs. parenteral administration**
  - **Allows for improved biologic pharmacokinetics and pharmacodynamics**
  - **Can be used for oral delivery of hundreds of biologics**
- **RaniPill pipeline programs**
  - **RT-111: ustekinumab for psoriasis**
  - **RT-102: PTH for osteoporosis**
  - **RT-105: adalimumab for psoriatic arthritis**
  - **RaniPill High Capacity (HC)**
    - **20 mg+ capacity**
    - **Materially increases number of potential drug candidate partners**
- **Strategic partnership with Celltrion for biosimilars**
- **Supportive safety, tolerability and pharmacokinetic data for proof of concept trials**
  - **Well tolerated & no serious adverse events in three Phase I studies**
- **Global rights to intellectual property**

[4] Rani Therapeutics 2023 Form 10-K, Filed March 20, 2024

PROJECTED FINANCIALS

Rani Therapeutics Holdings, Inc. - Income Statement

RANI Therapeutics, Inc.	2022 A	Q1 A	Q2 A	Q3 A	Q4 A	2023 A	2024 E	2025 E
Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$36,607	$9,712	$11,086	$11,220	$7,606	$39,624	$35,000	$37,000
General & Administrative	$26,844	$6,804	$7,208	$6,635	$5,828	$26,475	$20,000	$21,500
Operating Income	($63,451)	($16,516)	($18,294)	($17,855)	($13,434)	($66,099)	($55,000)	($58,500)
Operating Margin								
Interest Income, net	$177	$891	$896	$839	$675	$3,301	$2,700	$1,000
Other Income (Loss)	$0	($1,207)	($1,266)	($1,316)	($1,296)	($5,085)	$0	$0
Loss Before Income Taxes	($63,274)	($16,832)	($18,664)	($18,332)	($14,055)	($67,883)	($52,300)	($57,500)
Income Tax	($70)	$0	$0	$0	$0	$0	$0	$0
Non-Controlling Interest	($32,756)	($8,460)	($9,361)	($9,135)	($6,957)	($33,913)	($25,627)	($28,175)
Net Loss	**($30,588)**	**($8,372)**	**($9,303)**	**($9,197)**	**($7,098)**	**($33,970)**	**($26,673)**	**($29,325)**
Net Loss Per Share	**($1.28)**	**($0.33)**	**($0.37)**	**($0.36)**	**($0.27)**	**($1.33)**	**($1.00)**	**($0.82)**
Weighted Average Shares	23,817	25,240	25,345	25,552	25,874	25,505	26,660	35,760

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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HISTORICAL STOCK PRICE

Rani Therapeutics Holdings, Inc. – Share Price Chart[5]



[5] Source: Zacks Research System

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