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Rani Therapeutics Holdings, Inc. (RANI: NASDAQ)

RANI: 1Q:25 Financial 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 (5/16/2025)	$0.64
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. A deal for RT-114 was recently signed with ProGen for development of GLP-1/2 for obesity & diabetes.

Other Rani initiatives include development of larger capacity pills & collaborations with biopharmaceutical companies. Other efforts include the start of a 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	**5.74**
52-Week Low	**0.46**
One-Year Return (%)	**-88.3**
Beta	**0.1**
Average Daily Volume (sh)	**381,562**
Shares Outstanding (mil)	**58.5**
Market Capitalization ($mil)	**108.2**
Short Interest Ratio (days)	**0.4**
Institutional Ownership (%)	**10.9**
Insider Ownership (%)	**27.3**
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 2024 Estimate	**N/A**
P/E using 2025 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)
2024	$0.0 A	$0.0 A	$0.0 A	$1.0 A	$1.0 A
2025	$0.1 A	$0.0 E	$0.0 E	$0.0 E	$0.1 E
2026					$0.0 E
2027					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2024	-$0.29 A	-$0.26 A	-$0.24 A	-$0.27 A	-$1.05 A
2025	-$0.22 A	-$0.19 E	-$0.13 E	-$0.11 E	-$0.61 E
2026					-$0.45 E
2027					-$0.43 E

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WHAT'S NEW

On May 13th Rani Therapeutics Holdings, Inc. (NASDAQ: RANI) reported first quarter 2025 results. Year to date, Rani has updated investors on ProGen's PG102 asset and reported preclinical data for RT-114 and RT-116, or RaniPill semaglutide. In the financial sphere, the company paid down $3.8 million of debt and consumed ($12.0) million in operational expenses during 1Q:25. Rani's lead program, RT-114, produced favorable preclinical data demonstrating superior bioavailability compared to the underlying molecule's subcutaneous results. Most critically, Rani continues to interact with prospects to sign a deal with an established biopharmaceutical company which may include upfronts, milestones and royalties.

1Q:25 Operational and Financial Results

Rani reported first quarter results in a press release and Form 10-Q filing with the SEC on May 13th. For the quarter ending March 31st, 2025, revenues were $172,000, operating expense was ($12.0) million and net loss per share for Class A shareholders was ($0.22).

- Revenues of $172,000 were recognized representing an evaluation arrangement with a customer vs. $0;
- Research and development expenses totaled $6.6 million, down 13% from $7.6 million mostly due to lower compensation costs, a smaller team and reduced third party service costs;
- General & administrative expenses were $5.6 million, falling 13% from $6.4 million on lower compensation costs, reduction in workforce and lower other costs;
- Net interest expense was ($725,000) vs. ($745,000) due to lower cash balances;
- Non-controlling interest was ($5.5) million vs. ($7.3) million;
- Net loss for Class A shareholders was ($7.3) million vs. ($7.5) million or ($0.22) and ($0.29) per share.

As of March 31st, 2025, cash and marketable securities totaled $15.9 million. This amount compares to the $27.6 million balance held at the end of 2024. Long-term debt was held on the balance sheet at $24.6 million. 1Q:25 cash used in operations and for capital expenditures was ($8.2) million versus ($9.4) million in the same prior year period. During the first quarter, Rani repaid $3.8 million in debt, reducing the carrying value of debt outstanding to $20.9 million. Management expects cash to be sufficient to support operations until 3Q:25.

Research Agreement with Chugai

A May 19th press release informed investors that Rani had signed a research agreement with Chugai Pharmaceutical Co. on August 13th, 2024. The agreement granted Chugai rights to develop two molecules with undisclosed targets. Since the signing, the partner has demonstrated bioavailability comparable with delivery via the subcutaneous route for both molecules. The partners are now evaluating feasibility of applying Rani's technology to these antibodies.

RT-114 AND PG-102 Results

ProGen Collaboration Details
In June 2024, Rani announced a collaboration with ProGen Co., Ltd. to develop an oral obesity treatment combining ProGen's FC Fusion protein conjugated GLP-1/GLP-2 dual agonist, PG-102, with Rani's Rani Pill HC. Rani entered into a definitive agreement with ProGen to develop a new product designated RT-114, an oral dose of ProGen's PG-102. The companies will equally share the costs of development of RT-114 and divide geographies between them. Details of the arrangement between the two companies can be found in the second quarter 2024 Form 10-Q.[1]

Following the deal between Rani and ProGen, the partners have begun a development plan for the GLP-1/GLP-2 dual agonist. ProGen is conducting an ascending dose Phase I trial for PG-102 with the primary endpoints of safety and tolerability. Rani is advancing a head-to-head preclinical comparison of orally administered PG-102 using the RaniPill capsule (RT-114) to 16 healthy canines.

[1] See .pdf page 38 which is the beginning of the Collaboration Agreement listed as Exhibit 10.1

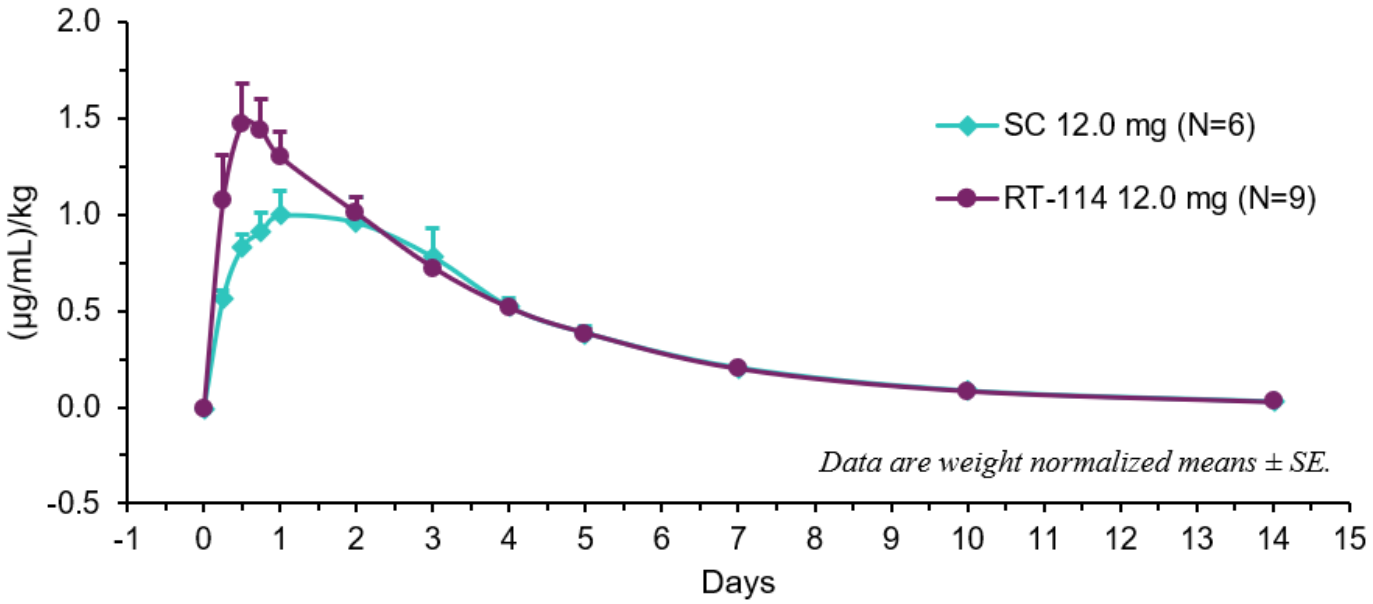
ProGen Clinical Trials

ProGen's Phase I trial underway for PG-102 announced preliminary results for the repeat-dose portion (Phase Ic) of its Phase I study. The candidate produced an average weight loss in subjects (N=73) of 4.8% after five weeks of dosing. Subcutaneous PG-102 was well tolerated with subjects able to titrate to the target dose in one month. There were no treatment discontinuations. Additional data was presented at the Asian Association for the Study of Diabetes (AASD) which was held March 28th to 30th. Rani's Senior Strategic Advisor, Jesper Høiland hypothesizes that the rapid titration may facilitate faster onset, shortening the time between initial administration and target weight loss. It is notable that the 4.8% average weight loss was achieved after five weeks compared to the four to five months required by approved GLP-1 agonists.[2] ProGen is planning a Phase II study of PG-102 that will compare the candidate with placebo in obesity and Type 2 diabetes. Six sites in Korea have been identified and sites outside Korea are also being added.

Rani Preclinical Trials

Rani is running its preclinical study, delivering either a 12 mg dose of PG-102 using RaniPill (N=10) or subcutaneously (N=6). This is estimated to be equivalent to a 60 mg dose in humans. The study is evaluating endpoints including safety, tolerability and reliability of the RaniPill capsule as well as pharmacokinetics, which is serum concentration measured by enzyme-linked immunosorbent assay (ELISA). Body weight and food intake are also being measured.

Exhibit I – Pharmacokinetics of RT-114 vs Subcutaneous PG-102



Source: Rani Therapeutics March 26, 2025 Press Release

Analysis of the data show that RaniPill was well tolerated with a safety profile comparable to subcutaneous delivery. RaniPill debris was excreted without sequelae in all dogs. Delivery success was 90% (9/10). RT-114 produced higher C_{MAX}, earlier T_{MAX} and relative bioavailability of 111% comparable to PG-102.

Exhibit II – C_{MAX}, T_{MAX} and AUC for RT-114 and Subcutaneous PG-102

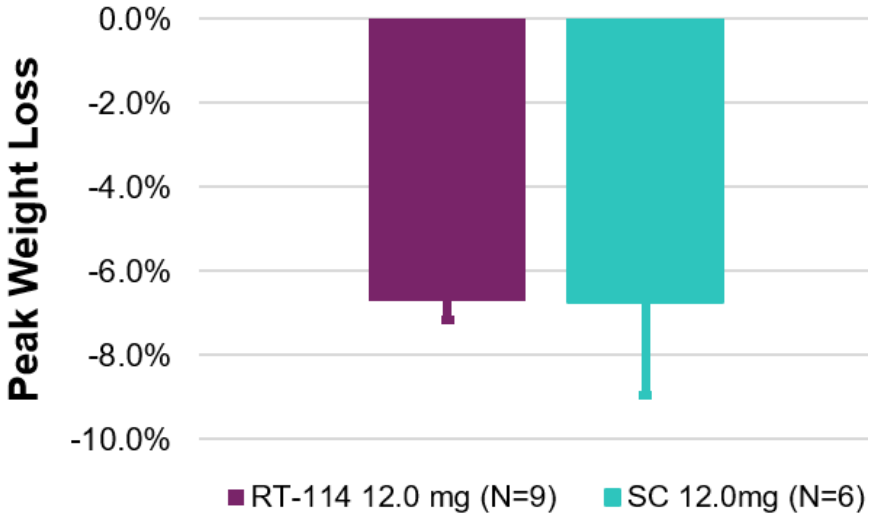
Route	C_{max} (µg/mL)/kg	T_{max} (days)	AUC_{last} (µg/mL*day)/kg
RT-114	1.51 ± 0.19	0.7 ± 0.1	5.48 ± 0.33
SC	1.06 ± 0.13	1.3 ± 0.3	4.92 ± 0.52

Source: Rani Therapeutics March 26, 2025 Press Release

Weight loss was the same in both the RaniPill group and the subcutaneous group, both equal to a 6.7% reduction over the observation period. The subcutaneous group had a greater variability in weight loss results compared with RT-114.

[2] Ryan, D.H., *et al*. Long-term weight loss effects of semaglutide in obesity without diabetes in the SELECT trial. Nature Medicine. May 2024. See Figure 1.

Exhibit III – Weight Loss in Canines for RT-114 vs. Subcutaneous PG-102



Source: Rani Therapeutics March 26, 2025 Press Release

designed as a multiple ascending dose study that will help identify the optimal dosing to be used in both ProGen's next stage of work and to inform the appropriate dose levels for the RT-114 program. ProGen has shared the results from the Phase Ia study which is evaluating subcutaneous delivery of PG-102. The study tested four dosing schemes which produced no gastrointestinal (GI) side effects in the first three doses and 30% incidence of GI side effects in the highest dose.[3] Additional data is expected in 2025. Rani must conduct a local toxicity study followed by the start of the Phase Ia clinical trials. RT-114 will be the subject of this 30-person open label safety study that will also examine pharmacokinetic and pharmacodynamic markers. Based on a preliminary view, a 15 mg and 30 mg pill will be compared to subcutaneous injection of 15 mg of PG-102 with each group evenly distributed. The study is expected to last from four to five months. A Phase Ic is also planned which will enroll 40 obese, non-diabetic subjects in another open label trial to examine PK and PD parameters. This study will look at repeat doses for four to seven weeks with a follow up. Trial duration is estimated at six to nine months with a start in 2025. The cost of the two Phase I studies is expected to range from $3 to $5 million with the costs split evenly between the partners.

A Phase IIa for obese patients providing 12 weeks of treatment is expected to follow the Phase I studies in 2026. Other studies will come later, including a pivotal study that will provide the data necessary for FDA and other regulatory body approval. Rani will be able to lean heavily on ProGen's work to support this effort. Based on our understanding of the partners' positions, we could see an FDA biologic license application (BLA) submission by 2029.

RT-116 Preclinical Results

The RT-116 program is evaluating one of the most important biologics in the market today: semaglutide. It is a successful treatment for weight loss and diabetes and can address other related conditions. An important shortcoming of the product is the lack of an effective oral formulation of the drug. RT-116 seeks to address this by using the RaniPill HC (RP) for delivery. Semaglutide is a GLP-1 receptor agonist that selectively binds to and activates the GLP-1 receptor mimicking its activity. GLP-1 is an incretin hormone and enterogastrone (hormone that slows stomach motility and secretion) that stimulates insulin secretion, inhibits glucagon secretion, delays gastric emptying and reduces the production of stomach acid serving as a physiological regulator of appetite and food intake.

Rani shared its preclinical readout from the RT-116 study demonstrating successful oral delivery of semaglutide using the RaniPill High Capacity (HC) device compared to subcutaneous (SC) injection. The study was conducted in eight canines to generate pharmacokinetic (PK) and pharmacodynamic (PD) data evaluating oral delivery of the GLP-1 agonist.

Study Design
This nonclinical PK and PD study was conducted to examine the effects of RT-116 versus a SC injection comparator group. It was designed as a 2x2 crossover study and was executed in two parts over four weeks. Eight canines were randomized into two equal groups who received either 0.5 mg of semaglutide delivered via the RP or subcutaneous injection. Endpoints include plasma drug concentrations, body weight, food intake, lipid profile and safety.

[3] Stifel Conference, November 18, 2024

Results

Semaglutide was successfully delivered in seven of the eight canines that received the RP, which was well-tolerated by all subjects with no serious adverse events (SAEs). C_{MAX}, T_{MAX} and area under the curve (AUC) were comparable for both modes of delivery.

Exhibit IV – Summary of RT-116 Study Endpoints

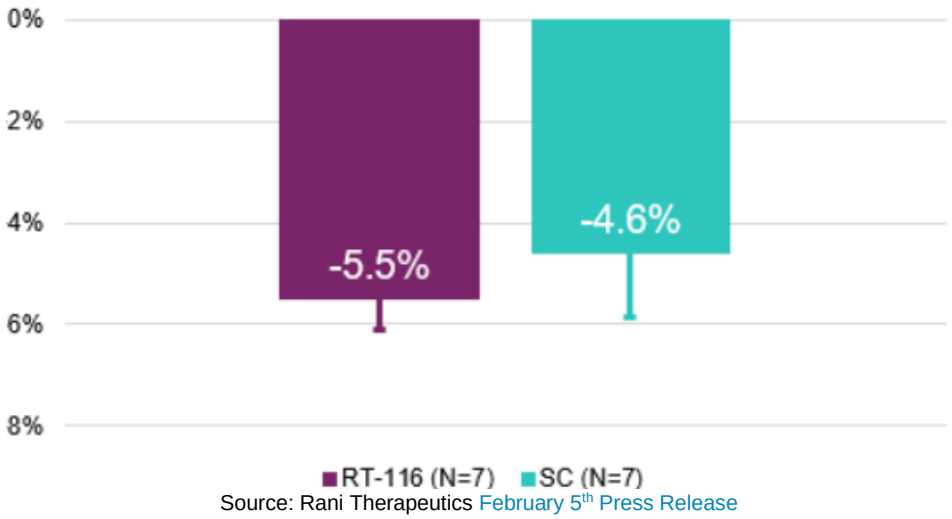
Route	C_{max} (ng/mL)	T_{max} (days)	T_{last} (days)	AUC_{last} (ng/mL*day)
Oral (RT-116)	941 ± 90	1.3 ± 0.3	17 ± 2	3630 ± 222
SC	948 ± 120	1.3 ± 0.3	17 ± 1	3390 ± 402

All data is mean ± standard error.

Source: Rani Therapeutics February 5th Press Release

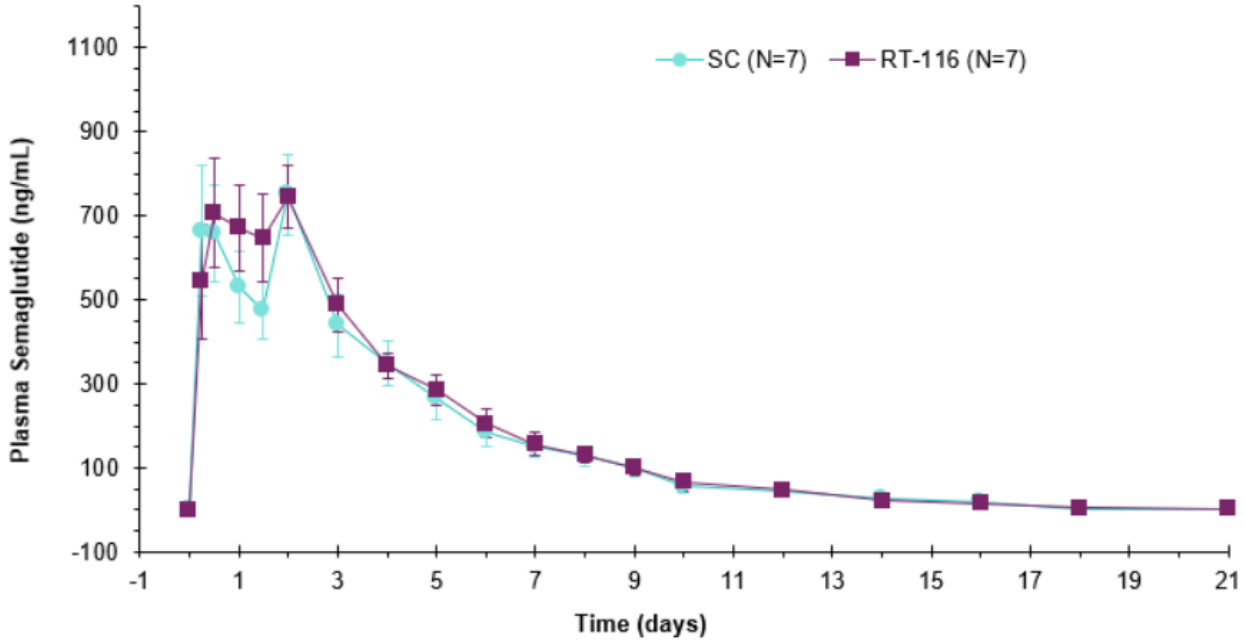
Oral administration of the RP generated similar bioavailability and biological activity comparable to subcutaneous administration with RP generating bioavailability of 107% of the subcutaneous method. Both groups produced similar weight loss and decreases in serum triglycerides and cholesterol.

Exhibit V – RT-116 Study Body Weight Loss



Source: Rani Therapeutics February 5th Press Release

Exhibit VI – Pharmacokinetic Profile of Semaglutide in Canines

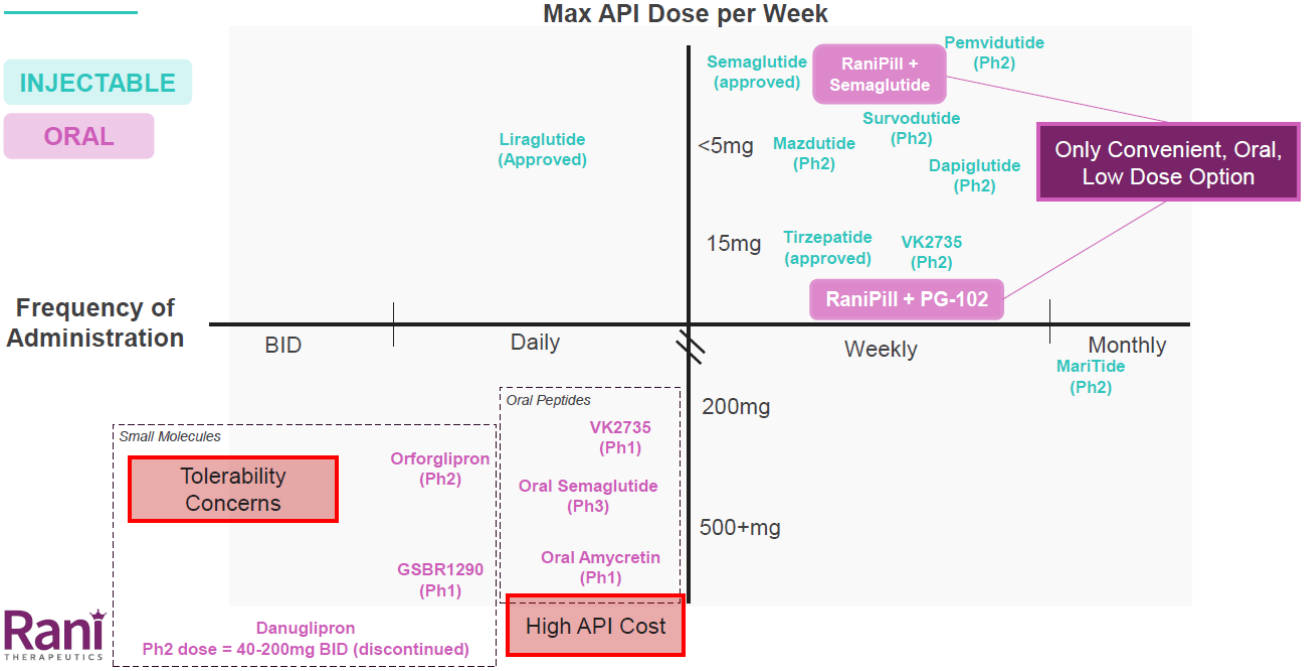


Source: Rani Therapeutics February 5th Press Release

RaniPill Opportunity

Rani management shared a graphic illustrating the frequency of administration versus the maximum active pharmaceutical ingredient (API) dose per week. It includes both injectable and oral products with administration frequency ranging from multiple times daily to monthly. Semaglutide, RaniPill semaglutide and RT-114 appear in the upper right quadrant. Of note, RaniPill products are expected to use similar quantities of underlying API as the injectable versions in contrast to some of the other oral formulations such as Rybelsus.

Exhibit VII – Obesity Landscape for RaniPill



Source: Rani Therapeutics 2024 Results Slide Deck, March 2025

RaniPill Børsen Review

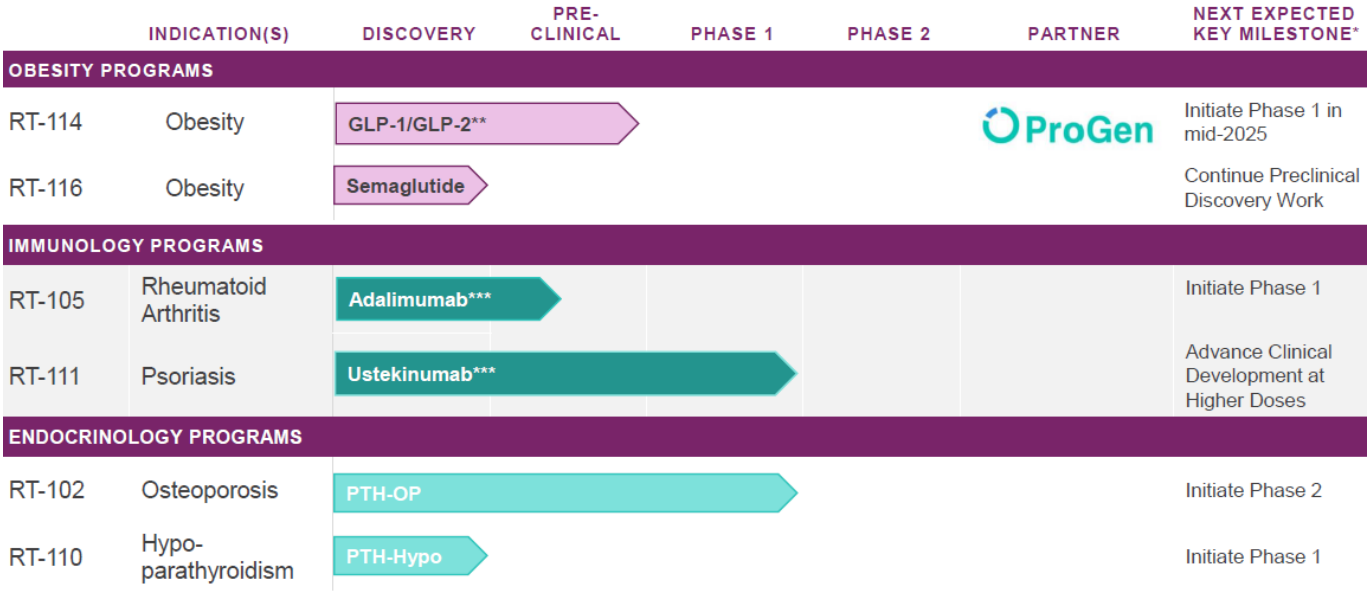
A recent article in the Danish financial publication, Børsen, drew a connection between semaglutide's sponsor, Novo Nordisk and Rani via a senior executive who previously served at the former and now acts as a Senior Strategic Advisor at the latter. We are referring to Jesper Høiland, who highlighted several synergies between the RaniPill and future opportunities for the semaglutide brands Ozempic, Mounjaro and Wegovy. Mr. Høiland recognizes the potential of the RP and anticipates a significant value inflection point when deals are signed with major pharmaceutical companies. The article highlighted that RP has been tested and administered more than 7,000 times in both animal models and humans with no safety problems. There have also been several clinical trials that tested a variety of medicines. Novo acquired the SNAC (Sodium N-[8-(2-hydroxybenzoyl)amino]caprylate) technology which is used in Rybelsus and has developed the LUMI (Luminal Unfolding Microneedle Injector) delivery system internally. However, Rybelsus is plagued with low bioavailability and LUMI it is in the early stages of development with no clinical data.

The RP could potentially extend the product life for Novo's semaglutide portfolio through the approval of an oral option with excellent levels of bioavailability. Using the 505(b)(2) pathway, a small trial could generate data sufficient to submit an application for an RP version of semaglutide to the FDA for approval. Mr. Høiland thinks that 2028 could be an important year for Rani as the semaglutide patent would have expired by then and the RP would have sufficient time to complete clinical trials and gain regulatory approval. The patent on the RP runs until 2044, which would provide many more years of protection for the underlying biologic. While Rani's Senior Strategic Advisor has not indicated whether or not he has communicated with Novo, he does see a natural fit between semaglutide and oral delivery technology.

Milestones

- Research agreement with Chugai Pharmaceutical – August 2024
- Participation in Maxim Healthcare Virtual Summit (webcast) – October 2024
- $10 million registered direct offering – October 2024
- Partnership development – 2025
- Preclinical data readout for RT-116 – February 2025
- Launch of Phase I trial for RT-114 – mid-2025

Exhibit VIII – Rani Therapeutic Pipeline



Source: Rani Therapeutics 2024 Results Slide Deck, March 2025

Summary

Rani reports first quarter results as its pipeline continues to advance. Rani needs to execute a deal in the near term and management is holding discussions. We feel that the Rani team is being careful to maintain an appropriate share of economic interest in any deal that takes place. Furthermore, the capital raising environment has been very tight due in large part to the economic uncertainty due to tariffs. Over the last few weeks, broader markets have re-gained some of their losses, which suggests that risk perceptions may have declined and capital markets and dealmakers may be more receptive. We maintain our valuation of $12.00 per share.

PROJECTED FINANCIALS

Rani Therapeutics Holdings, Inc. - Income Statement

RANI Therapeutics, Inc.	2024 A	Q1 A	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 E
Revenues	**$1,028**	**$172**	**$0**	**$0**	**$0**	**$172**	**$0**	**$0**
Research & Development	$26,682	$6,570	$6,410	$6,360	$6,225	$25,565	$26,588	$25,000
General & Administrative	$23,946	$5,615	$5,400	$5,272	$5,213	$21,500	$22,145	$23,000
Other Items	$3,714	$0	$0	$0	$0	$0	$0	$0
Operating Income	($53,314)	($12,013)	($11,810)	($11,632)	($11,438)	($46,893)	($48,733)	($48,000)
Operating Margin								
Interest Income, net	$1,763	$218	$105	$650	$550	$1,000	$950	$1,000
Other Income (Loss)	($5,033)	($943)	($920)	($920)	($920)	($3,703)	($3,600)	($3,600)
Loss Before Income Taxes	($56,584)	($12,738)	($12,625)	($11,902)	($11,808)	($49,596)	($51,383)	($50,600)
Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Non-Controlling Interest	($26,566)	($5,474)	($6,186)	($5,832)	($5,786)	($24,302)	($25,177)	($24,794)
Net Loss	**($30,018)**	**($7,264)**	**($6,439)**	**($6,070)**	**($6,022)**	**($25,294)**	**($26,205)**	**($25,806)**
Net Loss Per Share	**($1.05)**	**($0.22)**	**($0.19)**	**($0.13)**	**($0.11)**	**($0.61)**	**($0.45)**	**($0.43)**
Weighted Average Shares	28,476	33,440	33,600	45,000	55,000	41,760	58,000	60,000

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

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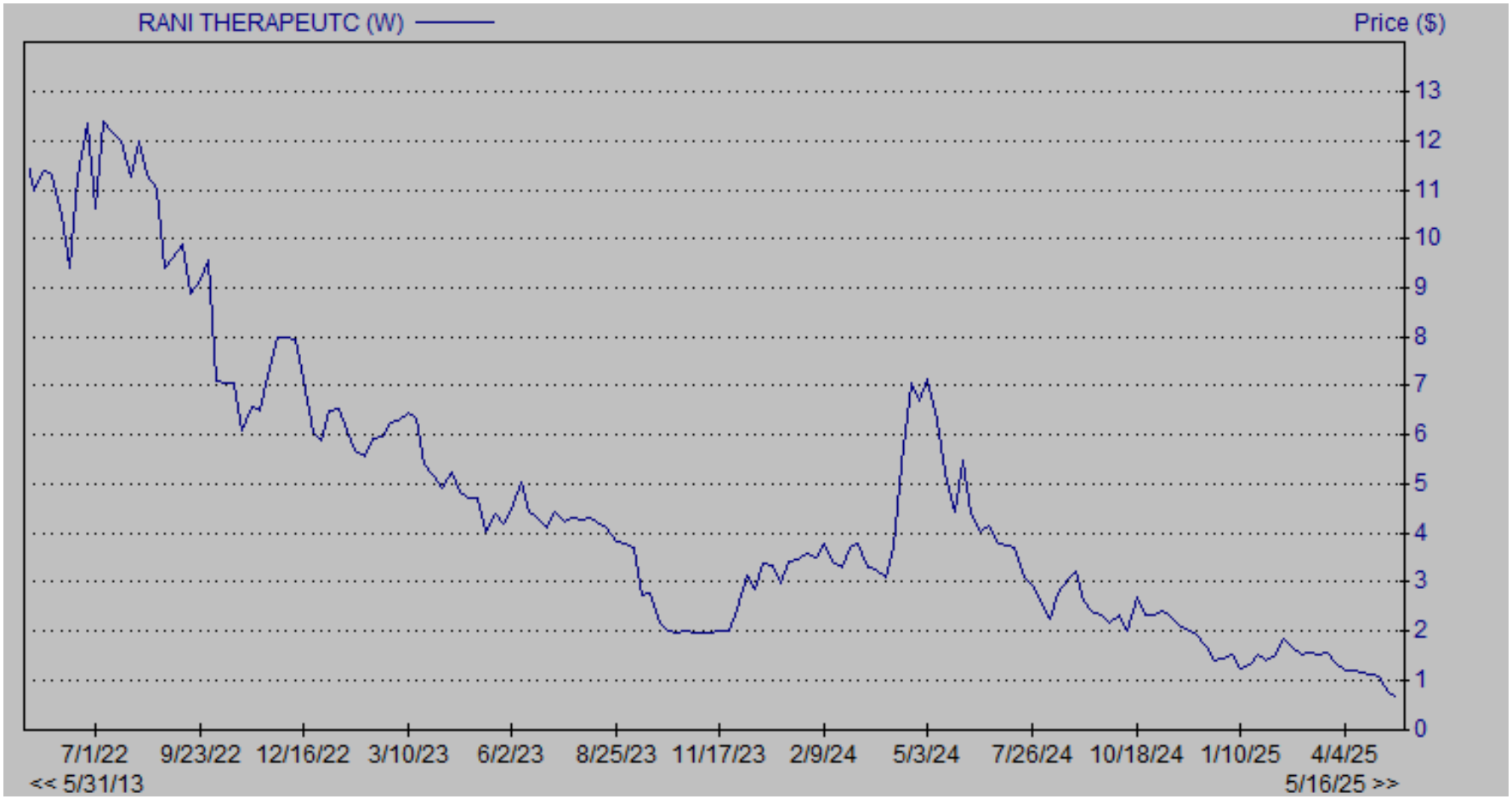
HISTORICAL STOCK PRICE

Rani Therapeutics Holdings, Inc. – Share Price Chart[4]



[4] Source: Zacks Research System

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