Zacks Small-Cap Research
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Rani Therapeutics Holdings, Inc. (RANI: NASDAQ)

RANI: GLP-2 Deal Announced

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 (6/27/2024)	$3.94
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. 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	**8.75**
52-Week Low	**1.82**
One-Year Return (%)	**-4.1**
Beta	**0.3**
Average Daily Volume (sh)	**146,974**
Shares Outstanding (mil)	**51.7**
Market Capitalization ($mil)	**203.7**
Short Interest Ratio (days)	**9.4**
Institutional Ownership (%)	**14.0**
Insider Ownership (%)	**48.9**
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)
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2024	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2025					$0.0 E
2026					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2023	-$0.33 A	-$0.37 A	-$0.36 A	-$0.27 A	-$1.33 A
2024	-$0.29 A	-$0.28 E	-$0.28 E	-$0.28 E	-$1.12 E
2025					-$0.89 E
2026					-$0.75 E

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WHAT'S NEW

Rani Therapeutics Holdings, Inc. (NASDAQ: 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. The press release describing the deal was followed by a conference call held the morning of June 24th, 2024. Rani has entered into a definitive agreement with this South Korean firm to develop RT-114, an oral dose of ProGen's PG-102, a GLP-1/GLP-2 dual agonist for treatment of obesity. The companies will equally share the costs of development and divide geographies between them.

Collaboration Details

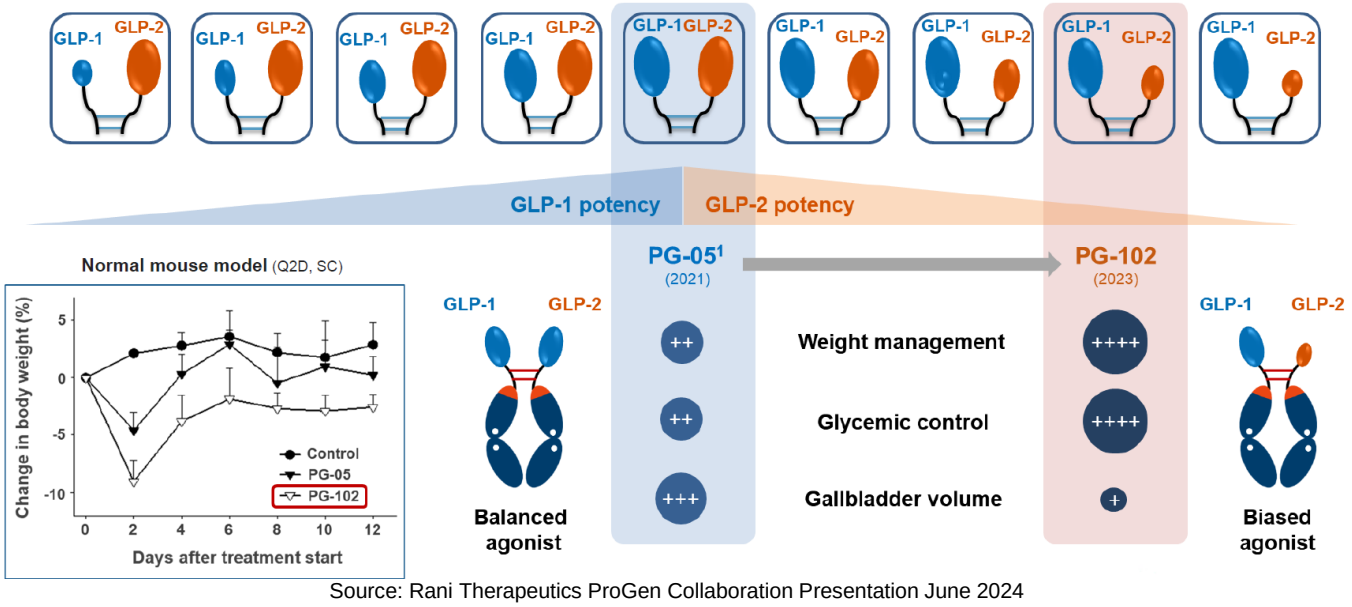
Rani and ProGen's collaboration seeks to advance a GLP-1/GLP-2 dual agonist for the treatment of obesity. While GLP-1 agonists have been thoroughly discussed in recent years there are other less well-known incretin hormones that are involved in intestinal growth and function. GLP-2s are less well publicized but offer several complementary benefits to GLP-1 agonists for weight loss. Rani is looking beyond the approved generation of therapy to a new one that will address existing drawbacks including side effects and loss of muscle mass. The collaboration agreement between the two companies will develop the Rani Pill high capacity (HC) capsule containing ProGen's PG-102 for weight management. The 50/50 worldwide revenue and cost share effort will initially focus commercialization on major markets. No initial payments will be made between the parties. Rani holds rights to commercialize in the United States, Europe, the United Kingdom, Canada and Australia. ProGen holds rights for all other areas, most importantly, Asia. Each party can sublicense in its territories. ProGen will manufacture the drug substance and Rani will manufacture the Rani Pill drug product.

The agreement with ProGen does not prevent Rani from pursuing other obesity and diabetes collaborations or partnerships. Management has ongoing contact with undisclosed prospects and a deal could be announced at any time not only for this category but others as well.

ProGen

ProGen was founded in 1998 and initially out-licensed cell lines to drug manufacturers. As the company matured, it shifted its focus towards research and development. In 2023 it was the subject of an initial public offering (IPO) on the Korean Exchange. It also began early trials for PG-102 that year and started research collaborations with several other life sciences companies for bispecific antibody drug conjugates (ADCs) and other molecules. The company's pipeline is focused on Type 2 diabetes, obesity and oncology. These candidates leverage ProGen's NTIG or Neo Tri-ImmunoGlobulin technology which is a platform optimized for the development of anti-cancer and immune disease treatments with multi-targeting and long-term durability.

Exhibit I – Evolution of PG-102



Source: Rani Therapeutics ProGen Collaboration Presentation June 2024

Next Steps

Now that the deal has been signed, the partners are looking forward to further trials. ProGen has a Phase I trial underway for PG-102 which is expected to produce data by November 2024. Rani will be required to conduct a local toxicity study and will then be ready to start clinical trials. A Phase Ia is planned for Rani's version of the product and RT-114 will be the subject of this 30-person open label safety study that will also examine pharmacokinetic and pharmacodynamic markers. 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 and begin in 2025. A Phase Ic is also planned which will enroll 40 obese, non-diabetic subjects in another open label trial that is examining 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 and is also expected to begin in 2025. The cost of the two Phase I studies is expected to raise from $3 to $5 million with the costs split evenly between ProGen and Rani.

Exhibit II – RT-114 Phase I Trial Design

Study Phase	1A	1C
Study Population	HV (BMI 18-30 kg/m^2)	Obese (non-diabetic) (BMI 30-39.9 kg/m^2)
Sample Size	30	40
Design	Open-label	Open-label
Objective(s)	▪ Safety (TEAEs & SAEs) ▪ PK ▪ BA ▪ PD marker	▪ Safety (TEAEs & SAEs) ▪ PK ▪ PD (% change in BW, lipids, glucose, insulin, C-peptide, glucagon)
Dose group(s)	▪ RaniPill 15 mg (N=10) ▪ RaniPill 30 mg (N=10) ▪ SC Injection 15 mg (N=10)	▪ Placebo (N=15) QW ▪ RaniPill XX mg (N=15) QW ▪ RaniPill XX mg (N=15) QM/Q2W
Treatment period (F/U)	Single ascending dose - 4 weeks F/U	Repeat Doses 4-7 weeks - 4 weeks F/U
Study duration	4-5 months	6-9 months

Source: Rani Therapeutics ProGen Collaboration Presentation June 2024

A Phase IIa for obese patients providing 12 weeks of treatment will follow the Phase I studies in 2026. Other studies will come after 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 position of each of the partners, we could see FDA biologic license application (BLA) submission by 2029.

GLP-2 Agonist Development

GLP-2 agonists are a drug class that imitate the action of glucagon-like peptide-2 (GLP-2), a naturally occurring hormone in the body. These drugs have been primarily used to treat certain gastrointestinal disorders in early clinical studies. For example, Ironwood Pharma is developing apraglutide for patients with short bowel syndrome due to the agonist's ability to stimulate intestinal growth and improve nutrient absorption. GLP-2s also are able to reduce inflammation which along with the enhancement in nutrient absorption make it an important complement to GLP-1 agonists which can lead to muscle loss along with weight loss and contribute to gastrointestinal side effects which may be alleviated by a reduction in inflammation.

Others that have initiated work on GLP-2 agonists include Takeda with teduglutide (Gattex) which is approved for short bowel syndrome, Zealand Pharma is entering the regulatory registration phase for glepaglutide, also in short bowel syndrome. The Korean Hanmi Pharmaceutical is investigating its HM15912 in an ongoing Phase II study for intestinal failure. Novo Nordisk, which is the whale in the GLP-1 space with semaglutide, is working on a long acting GLP-2 analogue. The private Naia Pharmaceuticals, which has not shown recent signs of activity, was also working on a GLP-2 candidate for short bowel syndrome.

There has not been much work done using GLP-2 agonists for diabetes and weight loss; however, its properties suggest that it would be a good complement to a GLP-1 agonist, addressing some of its weaknesses and potentially representing the next generation in

Rani Pill Advantage

We have enumerated (see our initiation) many of the benefits that Rani Pill (RP) brings to biologics delivery which were reiterated in the company's RT-114 presentation. RP provides better oral bioavailability for biologics, is able to improve dosing regimens and allow for daily administration. The robotic pill's flexible dosing allows for tighter therapeutic ranges which avoids the blood plasma peaks which may be associated with negative side effects and the troughs which are associated with reduced efficacy. Rani's RT-114 may allow for:

- Potentially no dose titration required
- Less drug substance required for therapeutic levels
- Tighter banding of serum concentrations

Milestones

- Topline results for RT-111 Phase I study – February 2024
- Presentations (2) of ustekinumab RT-111 data at Digestive Disease Week – May 2024
- Expiration of exclusive negotiation period with Celltrion – June 2024
- Launch of RT-102 Phase II study – 2024
- RaniPill HC Phase I trial – 2H:24
- Partnership development – 2024

Exhibit III – Rani Therapeutic Pipeline

	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

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

Summary

Rani will be best able to maximize the RP value if it licenses its technology as broadly as possible. One of the most exciting areas in the last year or two has been diabetes and weight loss, with GLP-1 agonists in the vanguard. An important weakness of biologics is that they require infusion to achieve reasonable levels of bioavailability and there are no strong competitors able to offer an oral option for biologics. With the RP, the oral possibility can be a reality and the fast growing $300 to $400 billion biologics market can exploit Rani's capabilities to improve delivery.

Rani's deal with ProGen is forward-looking and anticipates the next generation of diabetes and obesity medicine. While we see a longer and more capital intensive pathway forward, we also see a more relevant product that can address many of the shortcomings presented by the current crop of GLP-1 agonists. As is our practice, we do not value new programs until they are in the clinic and we have high conviction they will move forward. Rani plans to start its clinical program in 2025 at which time we will add the costs and benefits of RT-114 to the valuation. Rani's exclusive negotiation period with Celltrion has ended and now it may negotiate with others. The asset in question, RT-111, has shown high bioavailability for ustekinumab and an excellent safety profile. If Rani is able to find a partner here, this could provide upfront capital and a partner taking over the program, allowing Rani to allocate funds to other promising pipeline assets. We maintain our valuation of $12.00 per share.

PROJECTED FINANCIALS

Rani Therapeutics Holdings, Inc. - Income Statement

RANI Therapeutics, Inc.	2023 A	Q1 A	Q2 E	Q3 E	Q4 E	2024 E	2025 E	2026 E
Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$39,624	$7,586	$7,650	$7,700	$7,725	$30,661	$37,000	$38,480
General & Administrative	$26,475	$6,448	$6,100	$6,050	$6,025	$24,623	$21,500	$22,145
Operating Income	($66,099)	($14,034)	($13,750)	($13,750)	($13,750)	($55,284)	($58,500)	($60,625)
Operating Margin								
Interest Income, net	$3,301	$549	$700	$650	$600	$2,499	$1,000	$950
Other Income (Loss)	($5,085)	($1,294)	($1,200)	($1,200)	($1,200)	($4,894)	($4,800)	($4,800)
Loss Before Income Taxes	($67,883)	($14,779)	($14,250)	($14,300)	($14,350)	($57,679)	($62,300)	($64,475)
Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Non-Controlling Interest	($33,913)	($7,296)	($6,840)	($6,864)	($6,888)	($27,888)	($30,527)	($31,593)
Net Loss	**($33,970)**	**($7,483)**	**($7,410)**	**($7,436)**	**($7,462)**	**($29,791)**	**($31,773)**	**($32,882)**
Net Loss Per Share	**($1.33)**	**($0.29)**	**($0.28)**	**($0.28)**	**($0.28)**	**($1.12)**	**($0.89)**	**($0.75)**
Weighted Average Shares	25,505	26,034	26,655	26,671	26,692	26,513	35,760	44,125

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

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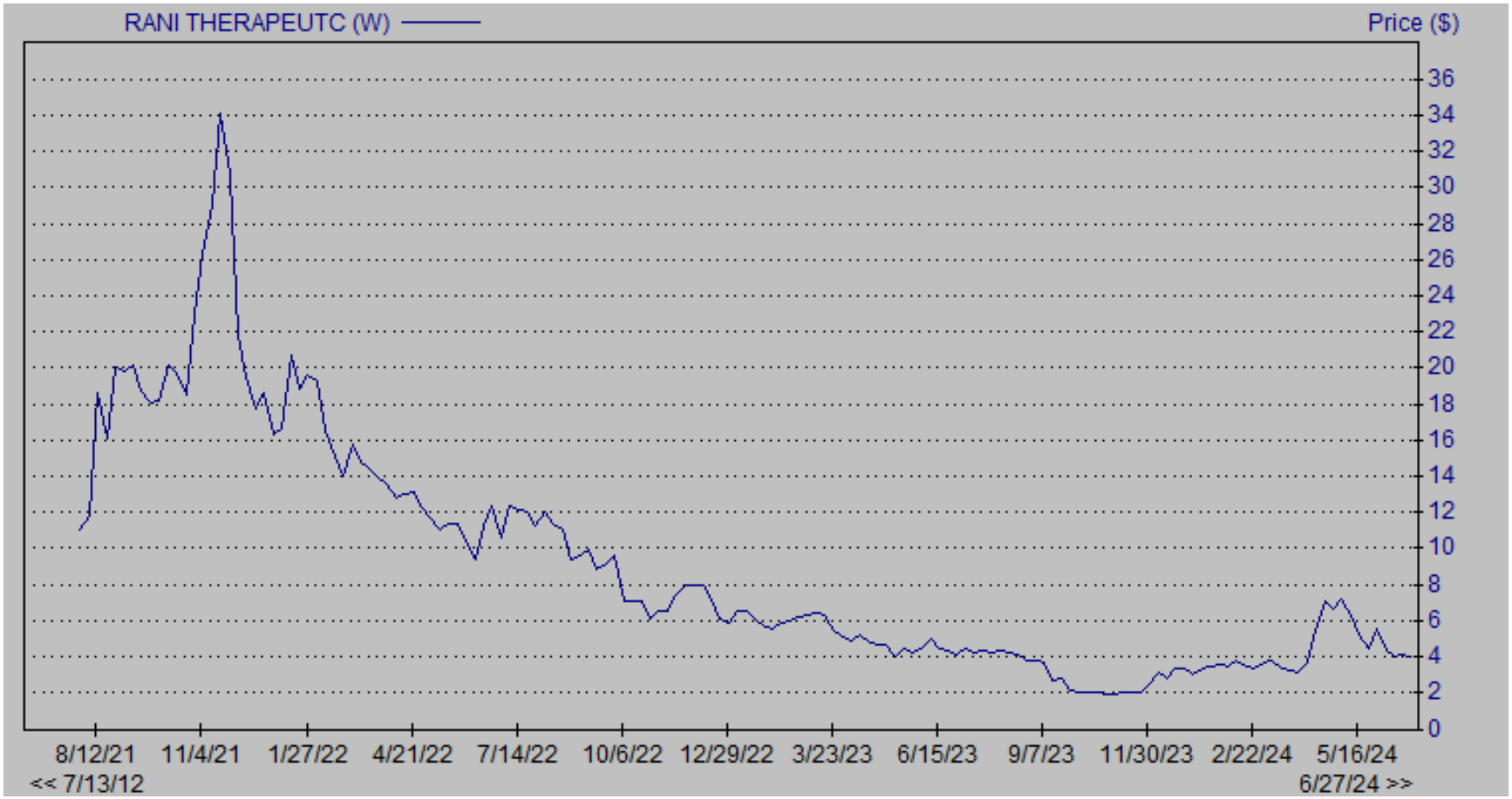
HISTORICAL STOCK PRICE

Rani Therapeutics Holdings, Inc. – Share Price Chart[1]



[1] Source: Zacks Research System

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