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November 20, 2024
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Rani Therapeutics Holdings, Inc. (RANI: NASDAQ)

RANI: Third Quarter Update

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 (11/19/2024)	$2.06
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	**8.75**
52-Week Low	**1.90**
One-Year Return (%)	**-38.1**
Beta	**0.1**
Average Daily Volume (sh)	**1,674,062**
Shares Outstanding (mil)	**58.5**
Market Capitalization ($mil)	**120.5**
Short Interest Ratio (days)	**0.4**
Institutional Ownership (%)	**19.6**
Insider Ownership (%)	**30.6**
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 A	$0.0 A	$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	-$0.26 A	-$0.24 A	-$0.28 E	-$1.06 E
2025					-$0.89 E
2026					-$0.75 E

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WHAT'S NEW

Rani Therapeutics Holdings, Inc. (NASDAQ: RANI) reported third quarter 2024 results on November 14th, 2024. Since the second quarter report, Rani has participated in multiple investor conferences, raised an additional $10 million and reported data for a GLP-1 incretin triagonist, which we review below. We are looking ahead to the completion of the preclinical work in preparation for the Phase I RT-114 study which is expected to begin in 2025. The other important anticipated event is a deal with an established biopharmaceutical company which may include upfronts, milestones and royalties for Rani. Management has shared that there are conversations underway to conclude a transaction but has not indicated when they may be realized.

Third Quarter 2024 Operational and Financial Results

Rani reported 3Q:24 results in a press release and Form 10-Q filing with the SEC on November 14th. The company did not hold a conference call. For the quarter ending September 30, 2024, revenues were zero, matching prior year amounts. Operating expense was $11.8 million and net loss per share for Class A shareholders was ($0.24).

- Research and development expenses totaled $6.2 million, down 45% from $11.2 million mostly due to lower payroll. Lower compensation cost was a result of the workforce reduction announced in November of 2023. Other year over year reductions were related to third-party service costs and materials and supplies expense;
- General & Administrative expenses were $5.6 million, falling 15% from $6.6 million on account of a reduction in the workforce, lower directors' and officers' insurance premiums partially offset by higher facility costs;
- Interest income was cut in half due to lower cash balances while interest expense was relatively stable;
- Non-controlling interest was ($5.9) million vs. ($9.1) million;
- Net loss for Class A shareholders was ($6.8) million vs. ($9.2) million or ($0.24) and ($0.36) per share.

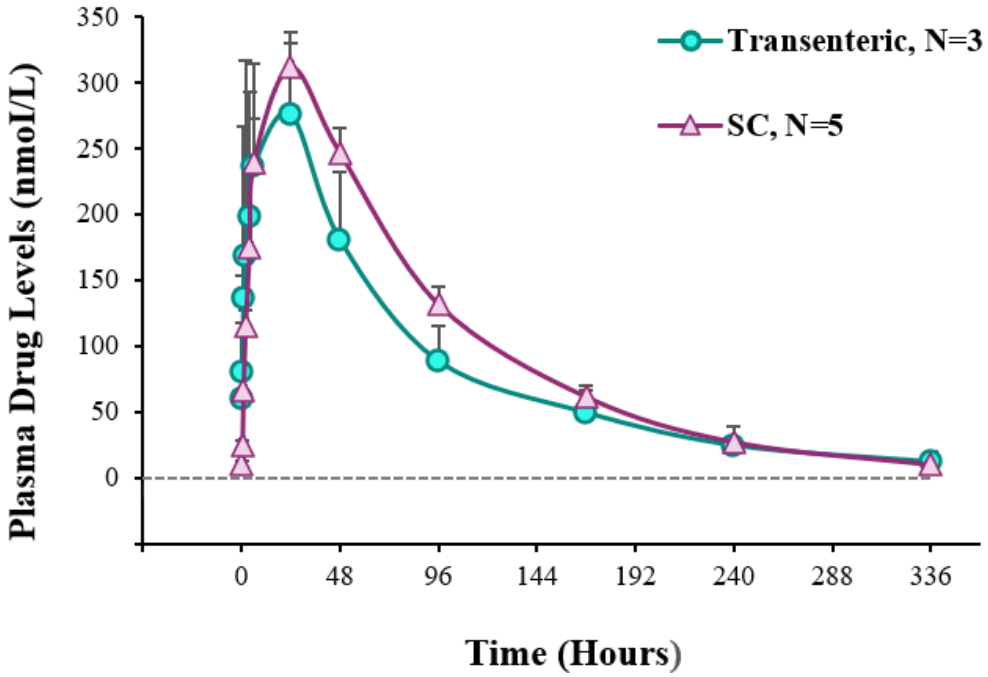
As of September 30, 2024, cash and marketable securities totaled $30.4 million. This amount compares to the $48.5 million balance held at the end of 2023. Long-term debt was held on the balance sheet at $28.3 million. 3Q:24 cash used in operations and for capital expenditures was ($8.5) million versus ($14.8) million for the comparable period in the prior year. For the first nine months of the year, cash burn was ($27.1) million vs. ($39.8) million. Following the end of the quarter and in October 2024, Rani sold securities to raise an additional $10 million in gross proceeds. Management expects cash to be sufficient to support operations until 3Q:25.

GLP-1 Incretin Triagonist Preclinical Data

In October, Rani provided a look at new preclinical data for a glucagon-like peptide-1 (GLP-1) incretin triagonist. The molecule reviewed in the press release demonstrated 80% bioavailability relative to subcutaneous delivery and produced weight loss over the measurement period in an animal model. The 8-subject study administered the incretin triagonist to canines. The molecule contains GLP-1, glucose-dependent insulinotropic polypeptide (GIP) and glucagon receptors. It was administered either through an endoscope-guided transenteric mechanism to mirror RaniPill administration or subcutaneous (SC) injection. The preclinical study evaluated the pharmacokinetic (PK) and pharmacodynamic (PD) profiles of the molecule which should provide further support for delivery using the Rani Pill.

The study consisted of two arms with three subjects in Group 1 which received the triagonist molecule via an endoscope-guided transenteric administration and five subjects that received the SC administration. Note that these are small numbers which lack statistical significance. For transenteric delivery, the area under the curve (AUC) in nmol*h/L was 26,963 and the concentration maximum (C_{MAX}) was 334. Time to maximum concentration was 16.7 hours. In the SC arm, AUC was 33,509 and C_{MAX} was 311. Time to maximum concentration was 24 hours. A representation of this data is in the exhibit below.

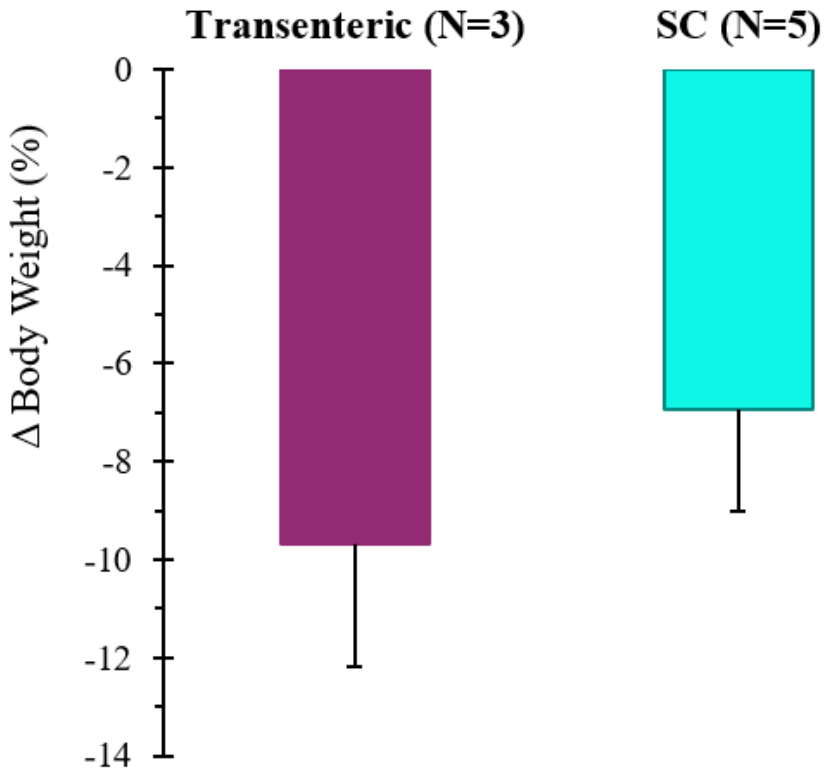
Exhibit I – PK Profile of Transenteric vs. SC Dose (0.12 mg/kg)



Source: Rani Therapeutics Press Release October 17, 2024

Data was collected over a two-week period for analysis of serum drug concentrations and various PD and safety biomarkers. Further analyses examined weight loss in the two study arms. Canines that received the transenteric delivery of drug saw a 9.7% decline in body weight while SC injected models saw a 6.9% decrease. The weight benefit was attributed to early satiety and reduced caloric intake. As a visual aid, peak decreases in body weights are provided in graphical form in the following exhibit. The time intervals for this metric were not given; however, peak weight loss was generally in a range of seven to eleven days after administration.

Exhibit II – Peak Decreases in Body Weights



Source: Rani Therapeutics Press Release October 17, 2024

RT-114 (GLP-1/GLP-2 dual agonist) ProGen Collaboration

With the triagonist preclinical effort complete, attention turns to the preclinical work necessary to begin the Phase Ia/Ic trial with RT-114. A PK study is required before going into the clinic and will also dose canines. However, the Rani Pill will be used rather than transenteric delivery in order to gain additional insight. Beyond the PK animal study, chemistry, manufacturing and controls (CMC) work must be completed, which is expected to be done before year end. The Phase Ia/Ic trial is on track for an early 2025 launch.

ProGen Collaboration Details
On June 24th, 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. 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 a new product designated RT-114. RT-114 is 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. Details of the arrangement between the two companies can be found in the second quarter 2024 Form 10-Q.[1]

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 on commercialization of 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.

Next Steps
Following the deal between Rani and ProGen, the partners are looking forward to further development trials for the GLP-1/GLP-2 dual agonist. ProGen has a Phase I trial underway for PG-102 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.[2] Additional data is expected in 2025. Rani is conducting a local toxicity study that should be complete around year end, followed by the start of the Phase Ia clinical trials next year. 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 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 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 follow, 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.

[1] See .pdf page 38 which is the beginning of the Collaboration Agreement listed as Exhibit 10.1
[2] Stifel Conference, November 18, 2024

Capital Raise

On October 15th, Rani announced pricing of a $10 million capital raise which has since closed. The transaction includes 3,000,000 shares of Rani Class A common stock and 333,333 pre-funded warrants to purchase Rani Class A common stock. Each share or pre-funded warrant included a common warrant with an exercise price of $3.00 per share with a life of five years. Each share and warrant were sold at a purchase price of $3.00. Along with the capital raise transaction, Rani has entered into an agreement with an investor to cancel all outstanding Series A common warrants issued on July 22, 2024. This totals 3,246,753 warrants. The deal closed shortly after the announcement and the funds have been added to the balance sheet.

Milestones

- Topline results for RT-111 Phase I study – February 2024
- Presentations 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
- Participation in H.C. Wainwright Global Investment Conference – September 2024
- Participation in Cantor Global Healthcare Conference – September 2024
- Participation in Maxim Healthcare Virtual Summit (webcast) – October 2024
- $10 million registered direct offering – October 2024
- Partnership development – 2024
- Launch of Phase I trial for RT-114 – 2025

Exhibit III – Rani Therapeutic Pipeline

	INDICATION(S)	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT EXPECTED KEY MILESTONE*
CORE PROGRAMS						
RT-114	Obesity	GLP-1/GLP-2**				Initiate Phase 1 in 2025
RT-111	Psoriasis	Ustekinumab***				Advance Clinical Development at Higher Doses
RT-102	Osteoporosis	PTH-OP				Initiate Phase 2
RT-105	Psoriatic Arthritis	Adalimumab***				Initiate Phase 1
RT-110	Hypo-parathyroidism	PTH-Hypo				Initiate Phase 1

Rani Therapeutics September 2024 Corporate Presentation

Summary

Rani reported third quarter results following a period where it released preclinical data for a new candidate, and raised additional capital while it continues talks for a deal with an established pharmaceutical company. Management noted progress on its preclinical work for RT-114 and the announced that the follow-on Phase Ia/Ic trial will start in early 2025. We maintain our valuation of $12.00 per share.

PROJECTED FINANCIALS

Rani Therapeutics Holdings, Inc. - Income Statement

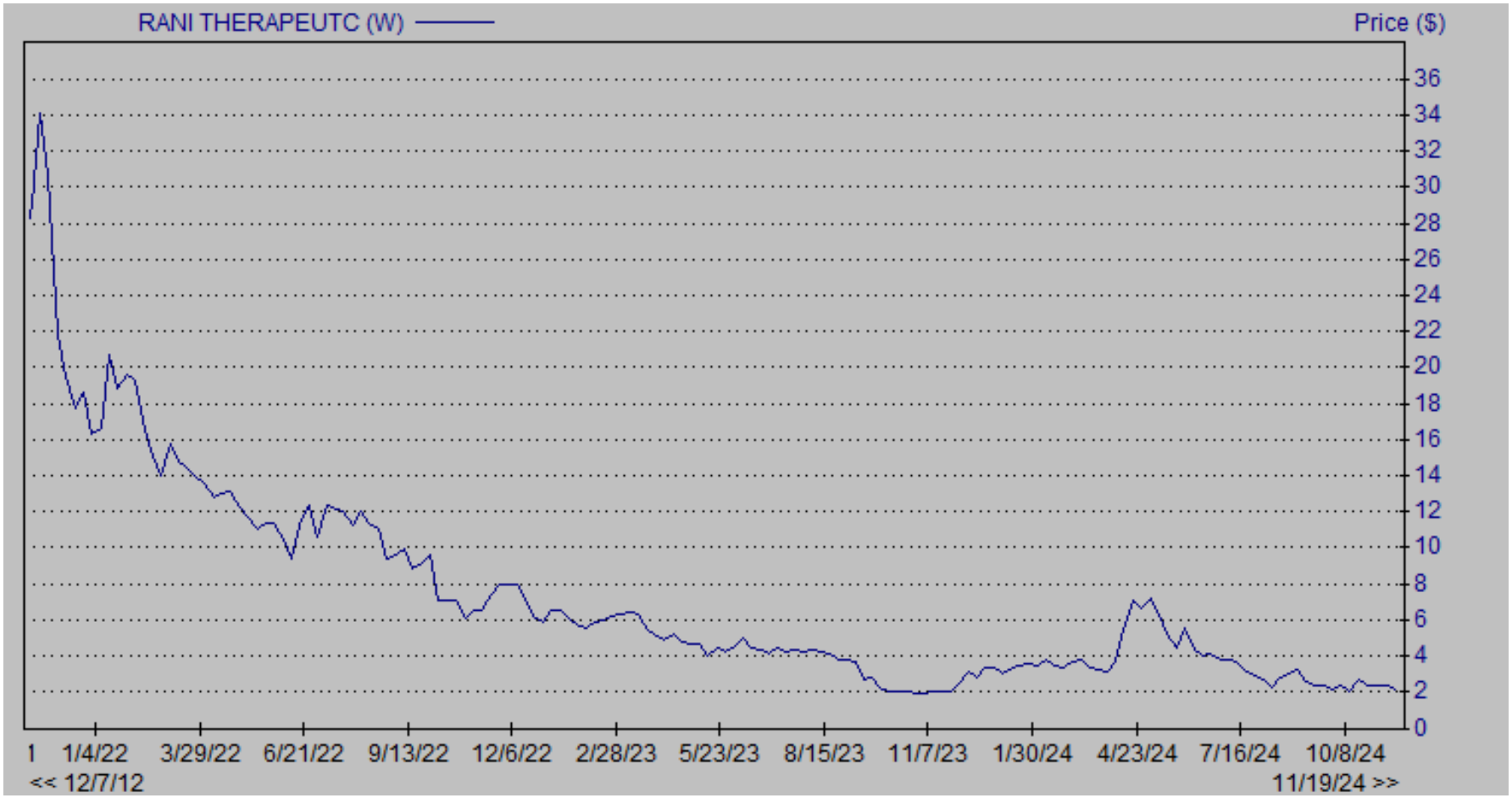
RANI Therapeutics, Inc.	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$39,624	$7,586	$6,115	$6,172	$7,725	$27,598	$37,000	$38,480
General & Administrative	$26,475	$6,448	$6,409	$5,627	$6,025	$24,509	$21,500	$22,145
Operating Income	($66,099)	($14,034)	($12,524)	($11,799)	($13,750)	($52,107)	($58,500)	($60,625)
Operating Margin								
Interest Income, net	$3,301	$549	$439	$414	$600	$2,002	$1,000	$950
Other Income (Loss)	($5,085)	($1,294)	($1,276)	($1,337)	($1,200)	($5,107)	($4,800)	($4,800)
Loss Before Income Taxes	($67,883)	($14,779)	($13,361)	($12,722)	($14,350)	($55,212)	($62,300)	($64,475)
Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Non-Controlling Interest	($33,913)	($7,296)	($6,556)	($5,939)	($6,888)	($26,679)	($30,527)	($31,593)
Net Loss	**($33,970)**	**($7,483)**	**($6,805)**	**($6,783)**	**($7,462)**	**($28,533)**	**($31,773)**	**($32,882)**
Net Loss Per Share	**($1.33)**	**($0.29)**	**($0.26)**	**($0.24)**	**($0.28)**	**($1.06)**	**($0.89)**	**($0.75)**
Weighted Average Shares	25,505	26,034	26,324	28,836	26,692	26,972	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[3]



[3] Source: Zacks Research System

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