Rani Therapeutics Reports Second Quarter 2024 Financial Results; Provides Corporate Update

August 6, 2024

- Announced partnership with ProGen on development of RT-114, an oral GLP-1/GLP-2 dual agonist for the treatment of obesity -

- Phase 1 study for RT-114 expected to initiate in 2025 -

- Completed equity offering with gross proceeds of approximately $10.0 million -

- Presented clinical and preclinical data on oral delivery of an ustekinumab biosimilar via the RaniPill® Capsule at Digestive Disease Week 2024 -

SAN JOSE, Calif., Aug. 06, 2024 (GLOBE NEWSWIRE) -- Rani Therapeutics Holdings, Inc. (“Rani Therapeutics” or “Rani”) (Nasdaq: RANI), a clinical-stage biotherapeutics company focused on the oral delivery of biologics and drugs, today reported financial results for the quarter ended June 30, 2024 and provided a corporate update.

“This quarter has been transformative for Rani, highlighted by the recent partnership with ProGen for the co-development and commercialization of RT-114, an oral RaniPill® capsule containing ProGen’s PG-102, a GLP-1/GLP-2 dual agonist, for the treatment of obesity,” said Talat Imran, Chief Executive Officer of Rani. “RT-114 has the potential to provide better lean muscle preservation and nutritional health of patients compared to current therapies due to the unique mechanism of action of GLP-2. We intend to evaluate RT-114 as a convenient, weekly oral dose. We look forward to initiating our Phase 1 study for RT-114 in 2025 with the aim of advancing a truly differentiated oral anti-obesity treatment option.”

Second Quarter 2024 and Subsequent Highlights:

- **Announced Partnership with ProGen on Development of Oral Obesity Treatment.** In June 2024, Rani announced that it has entered into a definitive agreement with ProGen Co., Ltd., a South Korean clinical-stage biotech company developing next generation long-acting, multi-specific fusion protein therapeutics, for the co-development and commercialization of RT-114, an oral RaniPill® capsule containing ProGen’s PG-102, a GLP-1/GLP-2 dual agonist, for the treatment of obesity. Under the terms of the collaboration agreement, Rani and ProGen agree to share responsibilities for the development and commercialization of RT-114 worldwide, including a 50/50 cost and revenue share arrangement. Rani has exclusive rights to lead development and commercialization of RT-114 in the United States, Europe, Canada and Australia, and ProGen has exclusive rights to lead development and commercialization in the rest of the world. Rani is designated to lead operationally in conducting preclinical and development activities through the Phase 1 program, which is expected to initiate in 2025.
- **Completed equity offering for total gross proceeds of approximately $10.0 million.** In July 2024, Rani completed the sale and issuance of Class A common stock, pre-funded warrants to purchase Class A common stock, and warrants to purchase Class A common stock, to an institutional investor for total gross proceeds of approximately $10.0 million, excluding any potential proceeds from the exercise of warrants, if any.
- **ProGen presented data from Phase 1 single-ascending dose study of PG-102, a GLP-1/GLP-2 dual agonist, at the 2024 American Diabetes Association conference.** PG-102 showed a favorable safety profile with lower frequencies of gastrointestinal side effects compared to competitors’ trials in similar settings.
- **Presented Clinical and Preclinical Data on Oral Delivery of an Ustekinumab Biosimilar via the RaniPill® Capsule at Digestive Disease Week 2024.** In May 2024, Rani presented clinical and preclinical data on the RaniPill® capsule, the company’s oral delivery platform, at Digestive Disease Week® (DDW). The clinical data presentation demonstrated that an orally administered robotic pill (RP) reliably and safely delivered an ustekinumab biosimilar RT-111 with high bioavailability relative to subcutaneous (SC) ustekinumab in healthy human participants. The preclinical data presentation demonstrated that an orally-administered ustekinumab biosimilar RT-111 delivered via a robotic pill yielded bioavailability comparable to subcutaneous injection in canines.

Near-Term Milestone Expectations:

- Initiation of Phase 1 clinical trial of RT-114 containing a GLP-1/GLP-2 dual agonist for the treatment of obesity expected in 2025.

Second Quarter 2024 Financial Results:

- **Cash, cash equivalents and marketable securities** as of June 30, 2024 totaled $30.9 million, compared to $48.5 million for the year ended December 31, 2023.
- **Research and development expenses** for the three months ended June 30, 2024 were $6.1 million, compared to $11.1 million for the same period in 2023. The decrease of $5.0 million was primarily attributed to lower compensation costs of

$2.9 million due to reduction in workforce, $1.6 million reduction in third-party services and $0.4 million reduction in materials and supplies due to the timing of certain preclinical and clinical studies.

- **General and administrative expenses** for the three months ended June 30, 2024 were $6.4 million, compared to $7.2 million for the same period in 2023. The decrease of $0.8 million was primarily attributed to lower compensation costs of $1.3 million due to reduction in workforce, offset by an increase in facility costs of $0.4 million due to the lease in Fremont, California.
- **Net loss** for the three months ended June 30, 2024 was $13.4 million, compared to $18.7 million for the same period in 2023, including stock-based compensation expense of $4.1 million for the three months ended June 30, 2024, compared to $5.1 million for the same period in 2023.

About Rani Therapeutics

Rani Therapeutics is a clinical-stage biotherapeutics company focused on advancing technologies to enable the development of orally administered biologics and drugs. Rani has developed the RaniPill capsule, which is a novel, proprietary and patented platform technology, intended to replace subcutaneous injection or intravenous infusion of biologics and drugs with oral dosing. Rani has successfully conducted several preclinical and clinical studies to evaluate safety, tolerability and bioavailability using RaniPill capsule technology. For more information, visit 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, RT-114 therapeutic potential, the expected initiation of a Phase 1 trial of RT-114 in 2025, the success of Rani’s collaboration with ProGen, Rani’s development and advancement of its RaniPill capsule technology, including RaniPill HC, Rani’s advancement of its preclinical and clinical programs and timing of results, the sufficiency of Rani’s cash reserves, the timing and extent of its expenses, and future financial performance. 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 “expect,” “intend,” “look forward,” “potential,” 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 and the other risks described in Rani’s filings with the Securities and Exchange Commission, including Rani’s annual report on Form 10-K for the year ended December 31, 2023 and subsequent filings and reports by Rani. 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.

Trademarks

Trade names, trademarks and service marks of other companies appearing in this press release are the property of their respective owners. Solely for convenience, the trademarks and trade names referred to in this press release 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.

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RANI THERAPEUTICS HOLDINGS, INC
Consolidated Balance Sheets
(In thousands, except par value)

	June 30, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 4,514	$ 5,864
Marketable securities	26,387	42,675
Prepaid expenses and other current assets	1,133	2,308
Total current assets	32,034	50,847
Property and equipment, net	5,695	6,105
Operating lease right-of-use asset	5,751	718
Other assets	246	246
Total assets	$ 43,726	$ 57,916
Liabilities and Stockholders' Equity		
Current liabilities:		

Accounts payable	$ 506	$ 648
Accrued expenses and other current liabilities	2,422	1,726
Current portion of long-term debt	12,290	4,897
Current portion of operating lease liability	1,363	718
Total current liabilities	16,581	7,989
Long-term debt, less current portion	17,207	24,484
Operating lease liability, less current portion	4,388	—
Total liabilities	38,176	32,473
Stockholders' equity:		
Preferred stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Class A common stock, $0.0001 par value - 800,000 shares authorized; 26,489 and 26,036 issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	3	3
Class B common stock, $0.0001 par value - 40,000 shares authorized; 24,116 issued and outstanding as of June 30, 2024 and December 31, 2023	2	2
Class C common stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Additional paid-in capital	90,012	85,762
Accumulated other comprehensive loss	(5)	(12)
Accumulated deficit	(87,177)	(72,889)
Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc.	2,835	12,866
Non-controlling interest	2,715	12,577
Total stockholders' equity	5,550	25,443
Total liabilities and stockholders' equity	$ 43,726	$ 57,916

RANI THERAPEUTICS HOLDINGS, INC
Consolidated Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 6,115	$ 11,086	$ 13,700	$ 20,798
General and administrative	6,409	7,208	12,857	14,012
Total operating expenses	$ 12,524	$ 18,294	$ 26,557	$ 34,810
Loss from operations	(12,524)	(18,294)	(26,557)	(34,810)
Other income (expense), net				
Interest income and other, net	439	896	988	1,787
Interest expense and other, net	(1,276)	(1,266)	(2,571)	(2,473)
Net loss	$ (13,361)	$ (18,664)	$ (28,140)	$ (35,496)
Net loss attributable to non-controlling interest	(6,556)	(9,361)	(13,852)	(17,821)
Net loss attributable to Rani Therapeutics Holdings, Inc.	$ (6,805)	$ (9,303)	$ (14,288)	$ (17,675)
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted	$ (0.26)	$ (0.37)	$ (0.55)	$ (0.70)
Weighted-average Class A common shares outstanding—basic and diluted	26,324	25,345	26,179	25,293