Rani Therapeutics Announces Strategic Program Prioritization, Expansion of Manufacturing and Plans to Streamline Business Operations to Support Near-Term Value Drivers and Long-Term Growth of the RaniPill® Technology Platform; Reports Preliminary Third Quarter 2023 Financial Results

November 1, 2023

- Cash runway extended into 2025 -

- Cash runway expected to extend beyond topline results from Phase 2 trial for RT-102, topline results from Phase 1 trial for RT-111, and development of RaniPill® HC to be Phase 1 ready -

- Expansion of manufacturing footprint is expected to enable increased scale and support capacity for potential partner programs -

- RT-101 program discontinued; RT-105 and RT-110 programs paused -

- The company will reduce its workforce by approximately 25% -

SAN JOSE, Calif., Nov. 01, 2023 (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 announced strategic prioritization of programs, expansion of its manufacturing and plans to streamline its business operations to support potential near-term value drivers and long-term growth. The plans include strategic prioritization of its key development programs, RT-102, RT-111 and the RaniPill® HC, expansion of its manufacturing footprint to support increased scale and partnerships, and cost reduction initiatives that align with Rani’s near-term goals. Anticipated cost savings are expected to support Rani’s operating plans into 2025.

“We are laser-focused on driving forward our key programs to create near-term value and fuel long-term growth. We are also expanding our manufacturing footprint to support scale for late-stage development and partnering. Further, the initiatives we are announcing today are expected to extend our cash runway, providing us with the resources for important readouts from our RT-102 and RT-111 programs, as well as development of the RaniPill® HC to be Phase 1 ready,” said Talat Imran, Chief Executive Officer of Rani Therapeutics. “While we are discontinuing our RT-101 program, we aim to continue to develop RT-105 and RT-110 when we have the appropriate resources to do so. Importantly, the collaborations we have signed with Celltrion remain in place. We are also announcing a reduction in our workforce, which is part of the cost cutting measures needed to move the company forward at this time. We remain committed to our mission of making oral biologics a reality for the millions of patients living with chronic conditions and thank all of our stakeholders for their ongoing support.”

As a result of the initiatives announced today, Rani expects to extend its cash runway into 2025. Rani has chosen to prioritize its RT-102, RT-111 and RaniPill® HC programs. Rani is also entering into a lease for approximately 33,000 square feet to expand its manufacturing footprint. Development of RT-101 will be discontinued, while the development of RT-105 and RT-110 will be paused. In addition, Rani will reduce its workforce by approximately 25%. Rani Therapeutics expects to incur a one-time restructuring expense of approximately $0.3 million, of which nearly all are cash expenditures related to severance. This restructuring is expected to be substantially completed by the end of the first quarter of 2024. A material portion of the expense is anticipated to be incurred in the fourth quarter of 2023.

Near-Term Milestone Expectations:

- Initiation of Phase 2 study of RT-102, a RaniPill® GO containing teriparatide for osteoporosis, expected in the fourth quarter of 2023.
- Topline results of Phase 1 study of RT-111, a RaniPill® GO containing ustekinumab biosimilar CT-P43, expected in the first quarter of 2024.
- Development of RaniPill® HC to be ready for potential Phase 1 trials in the second half of 2024.

Preliminary Third Quarter Financial Results:

Rani’s preliminary consolidated financial results for the third quarter ended September 30, 2023 are presented below, and the results are subject to finalization of Rani’s customary quarterly financial close processes, and could be subject to change.

- Rani estimates that cash, cash equivalents and marketable securities will be approximately $60.5 million as of September 30, 2023.
- Rani estimates that net loss will be between $17.0 million and $19.0 million for the third quarter of 2023, compared to $16.2 million for the third quarter of 2022, and between $53.0 million and $55.0 million for the nine months ended September 30, 2023, compared to $46.0 million for the nine months ended September 30, 2022. The net loss includes estimated stock-based compensation expense of approximately $5.0 million for the third quarter of 2023, compared to $4.4 million for the third quarter of 2022, and approximately $14.5 million for the nine months ended September 30, 2023, compared to $11.3 million for the for the nine months ended September 30, 2022.

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 is progressing two RaniPill® capsules, the RaniPill®GO and the RaniPill®HC. Rani has successfully conducted several preclinical and clinical studies to evaluate safety, tolerability and bioavailability using RaniPill® capsule technology. For more information, visit www.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, the expected timing of topline results from the RT-111 Phase 1 study in Q1 2024, the expected initiation of the Phase 2 study of RT-102 in 2023, the expected readiness of the RaniPill® HC for clinical development in the second half of 2024, the ability of expanded manufacturing footpoint to support scaling of manufacturing and partnering, the sufficiency of the company’s cash, cash equivalents and marketable securities to fund operations into 2025, the ability to streamline its business operations and to realize the cost-savings contemplated by such streamlining of business operations, reduction in workforce and other initiatives announced by the company, the sufficiency of the cash, cash equivalents and marketable securities to extend beyond the time required to achieve key milestones and development points for key programs, the company’s aim to continue to develop RT-105 and RT-110 when it has appropriate resources to do so, the amount and timing of the restructuring expense, the estimates of Rani’s preliminary consolidated financial results for the third quarter of 2023, customer acceptance of the RaniPill® capsule technology, and the potential benefits of the RaniPill® capsule technology. 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 “expected,” “potential,” “aim,” “estimate,” “plans to” 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, 2022, 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.

Investor Contact:

investors@ranitherapeutics.com

Media Contact:

media@ranitherapeutics.com