



## Rani Therapeutics Unveils High-Capacity RaniPill™ Device For Oral Delivery of Biologics; Reports Preliminary 2021 Consolidated Financial Results

February 23, 2022

- Preclinical data demonstrates new RaniPill™ HC (High Capacity) delivered 500%-plus higher payloads than current RaniPill™ capsule
- Up to 20mg payload has the potential to unlock more than 50 additional biologics for internal development or partnership
- Company announces preliminary consolidated financial results for the fourth quarter and year ended December 31, 2021

SAN JOSE, Calif., Feb. 23, 2022 (GLOBE NEWSWIRE) -- Rani Therapeutics Holdings, Inc. ("Rani Therapeutics" or "Rani") (Nasdaq: RANI), a clinical-stage biotherapeutics company focused on the oral delivery of biologics, today announced the development of a high-capacity oral biologics device known as the RaniPill™ HC (High Capacity), capable of delivering up to a 500%-plus higher drug payload than Rani's existing oral biologics capsule. In preclinical testing, RaniPill™ HC demonstrated successful delivery of adalimumab and achieved high bioavailability.

"The RaniPill™ HC gives us the potential to deliver a much broader range of biologic drugs with its higher capacity of up to 20mg of drug per capsule," said Mir Imran, Rani's founder and Executive Chairman. "In addition, since the RaniPill™ HC shares many similarities with our existing RaniPill™ capsule, we are confident in our ability to achieve similar safety and performance metrics, and to leverage our existing investments in manufacturing and automation."

Today, biologics are predominantly delivered via injection or intravenous infusion, which limits long-term treatment adherence, often leading to suboptimal patient outcomes. An equally effective oral alternative could change the treatment paradigm for a number of patient populations, including those with autoimmune diseases, cancer, and diabetes.

"Therapeutic drug development has yielded a vast array of molecular entities, including peptides, antibodies and oligonucleotides. The new technology from Rani now allows for the potential oral administration of these drugs irrespective of their size or chemical nature," said Dr. Dennis Ausiello, a member of Rani's Board of Directors. Dr. Ausiello is the Director of the Center for Assessment Technology & Continuous Health (CATCH) and was previously Chief of Medicine at Massachusetts General Hospital.

Rani conducted a preclinical study of RaniPill™ HC, with each device containing an 18mg dose of the biologic adalimumab, a tumor necrosis factor (TNF)-α inhibitor that is approved for multiple autoimmune conditions including rheumatoid arthritis and Crohn's disease. The unencapsulated RaniPill™ HC device was placed laparoscopically in the jejunum of each of three canine test subjects and allowed to self-deploy under observation. Successful delivery was achieved in all cases, and systemic serum drug concentration was detected and measured over 5 days. A copy of the data is available on the Presentations page of Rani Therapeutics' investor relations website: <https://ir.ranitherapeutics.com/news-events/presentations>.

"The RaniPill™ HC is a major milestone for our platform technology. It opens up a significant number of opportunities for new pipeline drugs and partnerships," said Talat Imran, Rani's CEO. "This sets the stage for the rest of the year, as we anticipate moving two programs into the clinic using our existing RaniPill™ capsule, while also advancing development of the RaniPill™ HC for high-dose biologics. We believe these technologies have the potential to improve the lives of millions of patients with chronic diseases who currently depend on frequent injections."

### Preliminary Consolidated Financial Results

Rani's preliminary consolidated financial results for the three months and year ended December 31, 2021 are presented below, and the results are subject to finalization of the Company's customary quarterly and annual financial close processes.

- Rani estimates that net loss will be between \$13.0 million and \$15.0 million for the fourth quarter of 2021, compared to \$5.8 million for the fourth quarter of 2020, and between \$53.0 million and \$55.0 million for the full-year 2021, compared to \$16.7 million for full-year 2020. The net loss includes estimated equity-based compensation expense of approximately \$3.2 million for the fourth quarter of 2021 and approximately \$22.6 million for the full-year 2021. There was no equity-based compensation expense for the fourth quarter of 2020 nor full year-year 2020.
- Rani estimates that cash and cash equivalents will be approximately \$117.5 million as of December 31, 2021.

### Information Regarding Preliminary Results

The estimate of net loss and our cash and cash equivalents is preliminary and subject to completion, including the completion of audit procedures as of and for the year ended December 31, 2021. As a result, the unaudited preliminary net loss and cash and cash equivalents set forth above reflect our preliminary estimate with respect to such information, based on information currently available to management, and may vary from our actual consolidated financial position as of December 31, 2021. Further, this preliminary estimate is not a comprehensive statement or estimate of our consolidated financial results or financial condition as of and for the year ended December 31, 2021. Ernst & Young LLP, our independent registered public accounting firm, has not audited, reviewed, compiled, or performed any procedures with respect to the unaudited preliminary net loss or cash and cash equivalents. Accordingly, Ernst & Young LLP does not express an opinion or any other form of assurance with respect to the unaudited preliminary net loss and cash and cash equivalents. It is possible that we or Ernst & Young LLP may identify items that require us to make adjustments to the consolidated financial information. The information presented above should not be considered a substitute for the consolidated financial information to be filed with the Securities and Exchange Commission in our Annual Report on Form 10-K for the year ended December 31, 2021 once it becomes available and should not be regarded as a representation by us or our management as to our actual financial results for the three months or year ended December 31, 2021. The ranges for the preliminary estimated consolidated financial results described above constitute forward-looking

statements, are subject to change, and our actual financial results may differ from such preliminary estimates and such differences could be material. Accordingly, you should not place undue reliance upon these preliminary estimates.

### **Rani Therapeutics**

Rani Therapeutics is a clinical stage biotherapeutics company focused on advancing technologies to enable the development of orally administered biologics. Rani has developed the RaniPill™ capsules, which are a novel, proprietary and patented platform technology, intended to replace subcutaneous injection or intravenous infusion of biologics with oral dosing. Rani has successfully conducted several preclinical and clinical studies to evaluate safety, tolerability and bioavailability using RaniPill™ capsules. For more information, visit [ranitherapeutics.com](https://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, Rani’s preliminary consolidated financial results, Rani’s development and advancement of its RaniPill™ capsule technology, including RaniPill™ HC, the impact of its technology on medical treatment, Rani’s advancement of its preclinical and clinical programs, customer acceptance of the RaniPill™ capsule technology, the potential benefits of the RaniPill™ capsule technology, Rani’s prospects for entering into strategic partnerships or transactions, and Rani’s growth as a company. 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 “may,” “could,” “anticipate,” “believe,” “look forward,” “progress,” “advance,” “potential”, “be able 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, the impact of the COVID-19 pandemic, and the other risks described in Rani’s filings with the Securities and Exchange Commission. 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.

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