# Rani Therapeutics Reports First Quarter 2023 Financial Results; Provides Corporate Update

May 10, 2023

*- Announced partnership with Celltrion on development of RT-111, a RaniPill GO capsule containing a biosimilar for the monoclonal antibody ustekinumab -*

*- Received preliminary feedback from FDA on RT-102 development plans; 505(b)(2) pathway for RT-102 could be suitable -*

*- Initiation of Phase 2 clinical trial for RT-102 for the treatment of osteoporosis expected in 2H of 2023 -*

SAN JOSE, Calif., May 10, 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 reported financial results for the quarter ended March 31, 2023 and provided a corporate update.

“We started 2023 with great momentum when we announced a partnership with Celltrion on the development of our ustekinumab biosimilar for RT-111, a partnership that we believe validates RaniPill’s oral drug delivery technology,” said Talat Imran, Chief Executive Officer of Rani. “In addition, we received preliminary feedback from the FDA with respect to our RT-102 development plans, including the Phase 2 clinical trial that we intend to initiate in the second half of the year. Further, 2023 will be a crucial year for Rani as we commence three Phase 1 studies for RT-111, RT-105 and RT-110.”

**First Quarter Highlights:**

- **Announced partnership with Celltrion on development of an ustekinumab biosimilar for RT-111.** In January 2023, Rani announced a partnership with Celltrion for the development of RT-111, a RaniPill GO capsule containing Celltrion’s ustekinumab biosimilar (CT-P43) for the potential treatment of psoriatic arthritis, ulcerative colitis, Crohn’s disease and psoriasis. Rani was granted an exclusive license to use CT-P43 in the development and commercialization of RT-111, and Celltrion was granted a right of first negotiation to acquire worldwide rights to RT-111 following a Phase 1 clinical trial.
- **Preliminary feedback received from the U.S. Food and Drug Administration (“FDA”) on future development of RT-102.** Following feedback from a pre-Investigational New Drug meeting with the FDA, Rani believes that a 505(b)(2) pathway is suitable for the development of RT-102 in the U.S. In addition, Rani obtained guidance from the FDA on its preclinical and clinical development plans for RT-102, including the Phase 2 clinical trial which is expected to initiate in the second half of 2023.

**Near-Term Milestone Expectations:**

- Initiation of Phase 2 study of RT-102 for osteoporosis expected in the second half of 2023
- Initiation of three additional Phase 1 studies expected in 2023 with pipeline molecules:
  - RT-111 containing an ustekinumab biosimilar
  - RT-105 containing an adalimumab biosimilar
  - RT-110 containing parathyroid hormone for hypo-parathyroidism

**First Quarter Financial Results:**

- **Cash, cash equivalents and marketable securities** as of March 31, 2023 totaled $86.8 million, compared to cash, cash equivalents and marketable securities of $98.5 million for the year ended December 31, 2022. Rani expects its cash, cash equivalents and marketable securities to be sufficient to fund its operations to mid-2024.
- **Research and development expenses** for the three months ended March 31, 2023 were $9.7 million, compared to $7.6 million for the same period in 2022. The difference was primarily attributed to higher compensation costs of $1.9 million, which includes an increase of $0.4 million in stock-based compensation, due to headcount growth, and an increase of $0.4 million in facilities, materials and supplies expense related to preclinical and clinical development activities.
- **General and administrative expenses** for the three months ended March 31, 2023 were $6.8 million, compared to $6.2 million for the same period in 2022. The difference was primarily attributed to an increase in stock-based compensation of $1.1 million due to headcount growth, partially offset by a decrease in third-party services of $0.5 million due to non-recurring public company related costs.
- **Net loss** for the three months ended March 31, 2023 was $16.8 million, compared to $13.8 million for the same period in 2022, including non-cash charges primarily attributable to stock-based compensation expense of $4.0 million for the three months ended March 31, 2023, compared to $3.0 million for the same period in 2022.

**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, the expected initiation of a Phase 2 trial of RT-102 in the second half of 2023, the expected initiation of three Phase 1 trials of other product candidates in 2023, the impact achievement of upcoming clinical milestones could have on the business of the Company, the potential suitability of the 505(b)(2) pathway for RT-102 or other Rani programs, Rani’s advancement of its preclinical and clinical programs and timing of results, the sufficiency of Rani’s cash reserves for future operations, the timing and extent of its expenses, future financial performance, 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,” “expect,” “could,” “anticipate,” “look forward,” “progress,” “advance,” “intend” 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.

**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)**

| | March 31, 2023 (Unaudited) | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 18,984 | $ 27,007 |
| Restricted cash equivalents | 500 | 500 |
| Marketable securities | 67,803 | 71,475 |
| Prepaid expenses and other current assets | 1,751 | 1,942 |
| Total current assets | 89,038 | 100,924 |
| Property and equipment, net | 5,985 | 6,038 |
| Operating lease right-of-use asset | 1,423 | 1,065 |
| Total assets | $ 96,446 | $ 108,027 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,511 | $ 1,460 |
| Accrued expenses and other current liabilities | 2,716 | 2,349 |
| Operating lease liability, current portion | 923 | 1,006 |
| Total current liabilities | 5,150 | 4,815 |
| Operating lease liability, less current portion | 500 | 59 |
| Long-term debt | 29,207 | 29,149 |
| Total liabilities | 34,857 | 34,023 |
| Stockholders' equity: | | |
| Preferred stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of March 31, 2023 and December 31, 2022 | — | — |
| Class A common stock, $0.0001 par value - 800,000 shares authorized; 25,376 and 25,295 issued and outstanding as of March 31, 2023 and December 31, 2022, respectively | 3 | 3 |

| | | |
|---|---|---|
| Class B common stock, $0.0001 par value - 40,000 shares authorized; 24,116 issued and outstanding as of March 31, 2023 and December 31, 2022 | 2 | 2 |
| Class C common stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of March 31, 2023 and December 31, 2022 | — | — |
| Additional paid-in capital | 78,018 | 75,842 |
| Accumulated other comprehensive loss | (10) | (73) |
| Accumulated deficit | (47,291) | (38,919) |
| Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc. | 30,722 | 36,855 |
| Non-controlling interest | 30,867 | 37,149 |
| Total stockholders' equity | 61,589 | 74,004 |
| Total liabilities and stockholders' equity | $ 96,446 | $ 108,027 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| Operating expenses | | |
| Research and development | $ 9,712 | $ 7,591 |
| General and administrative | 6,804 | 6,189 |
| Total operating expenses | $ 16,516 | $ 13,780 |
| Loss from operations | (16,516) | (13,780) |
| Other income (expense), net | | |
| Interest income and other, net | 891 | 15 |
| Interest expense and other, net | (1,207) | — |
| Loss before income taxes | (16,832) | (13,765) |
| Income tax expense | — | (63) |
| Net loss | $ (16,832) | $ (13,828) |
| Net loss attributable to non-controlling interest | (8,460) | (7,605) |
| Net loss attributable to Rani Therapeutics Holdings, Inc. | $ (8,372) | $ (6,223) |
| Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted | $ (0.33) | $ (0.29) |
| Weighted-average Class A common shares outstanding—basic and diluted | 25,240 | 21,409 |