Rani Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results; Provides Corporate Update

March 22, 2023

- Anticipates initiating first Phase 2 clinical study in RT-102 in 2H of 2023 -

- Announced topline results from the Phase 1 repeat-dose study of RT-102 for the treatment of osteoporosis -

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

- Announced partnership with Celltrion on development of RT-111, a RaniPill GO capsule containing an ustekinumab biosimilar -

- Conference call and webcast today at 4:30 p.m. ET -

SAN JOSE, Calif., March 22, 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 and full year ended December 31, 2022 and provided a corporate update.

“The past year has proven transformative for Rani, highlighted by the positive topline Phase 1 results for RT-102 in osteoporosis and the unveiling of our high-capacity capsule, the RaniPill HC. We also announced the preclinical development of our oral ustekinumab program, RT-111, and earlier this year partnered with Celltrion to support the advancement of that program. These achievements mark significant milestones for the Company and are a testament to the hard work and dedication of the entire Rani team,” said Talat Imran, Chief Executive Officer of Rani. “In 2023, we anticipate continuing this momentum with the initiation of the Company’s first Phase 2 study in RT-102 as well as the initiation of Phase 1 studies with three additional pipeline assets. I look forward to providing updates throughout the year as we work to further solidify our commitment to developing orally delivered biologics and drugs.”

Fourth Quarter 2022 and Subsequent Highlights:

- **Announced topline results from Phase 1 study of RT-102.** In December 2022, Rani announced topline results from Part 2 (repeat-dose portion) of the Phase 1 study of RT-102. RT-102 is being developed for the treatment of osteoporosis. The study achieved all of its endpoints, with repeat doses of RT-102 being generally well tolerated and delivering drug with high reliability to participants via the RaniPill GO.
- **Preliminary feedback received from the U.S. Food and Drug Administration (“FDA”) on future development of RT-102.** Following feedback from a pre-IND meeting with 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 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.
- **Announced partnership with Celltrion on development of an ustekinumab biosimilar for RT-111.** In October 2022, Rani announced the preclinical development of RT-111, a RaniPill GO capsule containing a biosimilar of STELARA® (ustekinumab) for the potential treatment of psoriatic arthritis, ulcerative colitis, Crohn’s disease and psoriasis, all of which have large unmet medical needs for oral treatment. In January 2023, Rani announced a partnership with Celltrion for the development of RT-111. Rani was granted an exclusive license to use Celltrion’s ustekinumab biosimilar, 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.

Near-Term Milestone Expectations:

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

Full Year 2022 Financial Results:

- **Cash, cash equivalents, and marketable securities** as of December 31, 2022 totaled $98.5 million, compared to cash and cash equivalents of $117.5 million for the year ended December 31, 2021. There were no marketable securities in the prior comparative period. 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 and twelve months ended December 31, 2022 were $10.4 million and $36.6 million, respectively, compared to $7.4 million and $26.5 million for the same periods in 2021, respectively. The difference was primarily attributed to higher compensation costs of $6.6 million due to headcount growth, third-party services expense of $3.3 million and facilities, materials and supplies expense of $2.1 million due to increased preclinical and clinical development activities, partially offset by a decrease of $1.9 million in equity-based compensation due to our non-recurring initial public offering (IPO) and organizational transactions for the year ended December 31, 2021.
- **General and administrative expenses** for the three and twelve months ended December 31, 2022 were $7.1 million and $26.8 million, respectively, compared to $5.9 million and $27.8 million for the same periods in 2021, respectively. The difference was primarily attributed to higher compensation costs of $2.0 million due to headcount growth, third-party services of $1.6 million due to public company related costs, and travel expenses of $1.0 million, partially offset by a decrease of $4.9 million in equity-based compensation due to our non-recurring IPO and organizational transactions for the year ended December 31, 2021 and facility, material and supplies expenses of $0.6 million.
- **Net loss** for the three and twelve months ended December 31, 2022 was $17.3 million and $63.3 million, respectively, compared to $13.3 million and $53.1 million for the same periods in 2021, respectively, including non-cash charges primarily attributable to equity-based compensation expense of $4.0 million for the three months ended December 31, 2022 and $15.5 million for the full year 2022, compared to $3.3 million and $24.3 million for the same periods in 2021, respectively.

Conference Call

Rani will host a corresponding conference call and live webcast at 1:30 p.m. PT / 4:30 p.m. ET on March 22, 2023 to discuss the results and provide a business update. Individuals interested in listening to the live conference call may do so by using the webcast link in the “Investors” section of the company’s website at www.ranitherapeutics.com. A webcast replay will be available in the investor relations section on the company’s website for 90 days following the completion of the call.

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, the ability of the data from the Phase 1 study of RT-102 to support progressing to a Phase 2 trial of RT-102, 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 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)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 27,007	$ 117,453
Restricted cash equivalents	500	—
Marketable securities	71,475	—
Prepaid expenses and other current assets	1,942	2,142
Total current assets	100,924	119,595
Property and equipment, net	6,038	4,612
Operating lease right-of-use asset	1,065	—
Total assets	$ 108,027	$ 124,207
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,460	$ 1,080
Related party payable	53	126
Accrued expenses	2,296	1,434
Operating lease liability, current portion	1,006	—
Total current liabilities	4,815	2,640
Operating lease liability, less current portion	59	—
Long-term debt	29,149	—
Total liabilities	34,023	2,640
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Class A common stock, $0.0001 par value - 800,000 shares authorized; 25,295 and 19,712 issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	3	2
Class B common stock, $0.0001 par value - 40,000 shares authorized; 24,116 and 29,290 issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	2	3
Class C common stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Additional paid-in capital	75,842	55,737
Accumulated other comprehensive loss	(73)	—
Accumulated deficit	(38,919)	(8,331)
Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc.	36,855	47,411
Non-controlling interest	37,149	74,156
Total stockholders' equity	74,004	121,567
Total liabilities and stockholders' equity	$ 108,027	$ 124,207

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

	For the Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Contract revenue	$ —	$ —	$ —	$ 2,717
Operating expenses				
Research and development	10,386	7,417	36,607	26,482
General and administrative	7,097	5,945	26,844	27,834
Total operating expenses	$ 17,483	$ 13,362	$ 63,451	$ 54,316
Loss from operations	(17,483)	(13,362)	(63,451)	(51,599)
Other income (expense), net				
Interest income and other, net	818	16	1,248	89
Loss on extinguishment of debt	—	—	—	(700)
Interest expense and other, net	(719)	1	(1,071)	(466)

Change in estimated fair value of preferred unit warrant	—	—	—	(371)
Loss before income taxes	(17,384)	(13,345)	(63,274)	(53,047)
Income tax expense	41	40	(70)	(41)
Net loss	$ (17,343)	$ (13,305)	$ (63,344)	$ (53,088)
Net loss attributable to non-controlling interest	(8,556)	(8,116)	(32,756)	(44,757)
Net loss attributable to Rani Therapeutics Holdings, Inc.	$ (8,787)	$ (5,189)	$ (30,588)	$ (8,331)
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted	$ (0.35)	$ (0.27)	$ (1.28)	$ (0.43)
Weighted-average Class A common shares outstanding—basic and diluted	24,910	19,439	23,817	19,534