



Rani Therapeutics Reports Third Quarter 2022 Financial Results and Provides Corporate Update

November 10, 2022

- RT-102 Phase 1 topline repeat-dose data anticipated in 4Q 2022 -

- Announced preclinical development of RT-111, a RaniPill GO capsule containing ustekinumab biosimilar for the potential treatment of psoriatic arthritis, ulcerative colitis, Crohn's disease and psoriasis -

- Announced RT-102 Phase I single-dose topline results -

SAN JOSE, Calif., Nov. 10, 2022 (GLOBE NEWSWIRE) -- Rani Therapeutics Holdings, Inc. ("Rani Therapeutics" or "Rani") (Nasdaq: RANI), a clinical-stage biopharmaceuticals company focused on the oral delivery of biologics and drugs, today reported financial results for the quarter ended September 30, 2022, and provided a corporate update.

"I am delighted with what Rani has been able to accomplish so far this year, highlighted by the recent announcements of the latest RaniPill program RT-111, and positive topline data from Part 1 of the Phase 1 study of RT-102," said Talat Imran, Chief Executive Officer of Rani Therapeutics. "In the remainder of the year, we expect to announce topline data from Part 2 of the Phase 1 study of RT-102, which will provide the first repeat-dose data of the RaniPill capsule in humans. Additionally, we intend to continue to build out the RaniPill platform by beginning in vivo studies of a fully-autonomous RaniPill HC by year-end. Turning to 2023, we expect to initiate a Phase 2 study of RT-102 and to progress three additional assets into Phase 1 studies during the year as we advance the clinical development of our pipeline."

Third Quarter 2022 and Subsequent Highlights

- **Announced the preclinical development of RT-111.** In October 2022, the company announced that it had begun preclinical development of RT-111, a RaniPill GO containing a biosimilar of STELARA® (ustekinumab) for the potential treatment of psoriatic arthritis, ulcerative colitis, Crohn's disease and psoriasis. Rani intends to initiate a Phase 1 study for RT-111 in 2023.
- **Announced Positive Topline Phase 1 Results for RT-102.** In August 2022, Rani announced positive topline results from Part 1 of the Phase 1 clinical study of RT-102, the RaniPill GO containing a proprietary formulation of human parathyroid hormone (PTH) for the potential treatment of osteoporosis. RT-102 was generally well-tolerated and orally delivered 20µg and 80µg of PTH with 300-400% greater bioavailability of PTH than subcutaneous Forteo® (teriparatide) 20µg. Rani anticipates announcing topline data from Part 2 of the Phase 1 study in the fourth quarter of 2022.
- **Entered into a Loan Agreement with Avenue Venture Opportunities.** In August 2022, Rani entered into a loan and security agreement and related supplement with Avenue Venture Opportunities Fund, L.P. The loan agreement provides for term loans in an aggregate principal amount up to \$45.0 million. A loan of \$30.0 million was committed at closing, with \$15.0 million funded immediately and \$15.0 million available to be drawn between October 1, 2022 and December 31, 2022. The remaining \$15.0 million of loans is uncommitted and is subject to certain conditions and approval by the lender.
- **Entered into a Sales Agreement for "At-the-Market Offerings."** In August 2022, Rani entered into a Controlled EquitySM Sales Agreement with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC, collectively the Agents, pursuant to which Rani may offer and sell from time to time through the Agents up to \$150 million of shares of its Class A common stock, in such share amounts as Rani may specify by notice to the Agents, in accordance with the terms and conditions set forth in the sales agreement.

Expected Near-Term Milestones

- RT-102 – Phase 1 Part 2 topline repeat-dose data expected in the fourth quarter of 2022
- RT-102 – Investigational New Drug (IND) application, followed by Phase 2 initiation in the second half of 2023
- Initiation of three additional Phase 1 studies in 2023 with pipeline molecules:
 - RT-105 containing an adalimumab biosimilar
 - RT-110 containing PTH for hypo-parathyroidism
 - RT-111 containing an ustekinumab biosimilar for psoriatic arthritis, ulcerative colitis, Crohn's disease and psoriasis

Third Quarter Financial Results

- **Cash, cash equivalents, restricted cash equivalents and marketable securities** as of September 30, 2022 totaled \$98.7 million, compared to cash and cash equivalents of \$117.5 million for the year ended December 31, 2021. There were no restricted cash equivalents or marketable securities in the prior comparative period.
- **Research and development expenses** for the three months ended September 30, 2022 were \$9.1 million, compared to \$12.0 million for the same period in 2021. The difference was primarily attributed to a decrease of \$4.9 million in equity-based compensation due to Rani's non-recurring initial public offering (IPO) and related organizational transactions

in the three months ended September 30, 2021, partially offset by an increase of \$1.7 million in salaries and related benefit costs due to higher headcount, and an increase in facilities, materials and supplies expenses of \$0.5 million.

- **General and administrative expenses** for the three months ended September 30, 2022 were \$7.2 million, compared to \$15.8 million for the same period in 2021. The difference was primarily attributed to a decrease of \$9.4 million in equity-based compensation due to Rani's non-recurring IPO and related organizational transactions in the three months ended September 30, 2021, partially offset by an increase of \$0.4 million in salaries and related benefit costs due to higher headcount, and an increase of \$0.4 million in third-party services and other costs.
- **Net loss** for the three months ended September 30, 2022 was \$16.2 million, compared to \$28.7 million for the same period in 2021, including \$4.6 million and \$19.6 million of non-cash charges, primarily equity-based compensation expense, for the three months ended September 30, 2022 and 2021, respectively.

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 timing of topline results from the repeat-dose portion of Rani's Phase 1 trial of RT-102, the expected initiation of in vivo studies with a fully-autonomous RaniPill HC, the expected filing of an IND and initiation of a Phase 2 trial of RT-102 in 2023, the expected initiation of three Phase 1 trials of other product candidates in 2023, expected progress with the RaniPill HC platform, 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 and timing of results, customer acceptance of the RaniPill capsule technology, the potential benefits of the RaniPill capsule technology, the sufficiency of Rani's cash reserves, availability of additional tranches under its loan agreement, the potential to undertake "at-the-market offerings" of equity securities under its sales agreement with Agents, 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, the impact of the COVID-19 pandemic, 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, 2021 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 Condensed Consolidated Balance Sheets (In thousands, except par value)

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 27,219	\$ 117,453
Marketable securities	70,952	—
Prepaid expenses and other current assets	2,549	2,142
Total current assets	100,720	119,595
Restricted cash equivalents	500	—

Property and equipment, net	5,680	4,612
Operating lease right-of-use asset	1,302	—
Total assets	<u>\$ 108,202</u>	<u>\$ 124,207</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,790	\$ 1,080
Related party payable	55	126
Accrued expenses	4,357	1,434
Operating lease liability, current portion	984	—
Total current liabilities	<u>7,186</u>	<u>2,640</u>
Operating lease liability, less current portion	318	—
Long-term debt	<u>14,091</u>	<u>—</u>
Total liabilities	21,595	2,640
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value - 20,000 shares authorized; none issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Class A common stock, \$0.0001 par value - 800,000 shares authorized; 24,720 and 19,712 issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	2	2
Class B common stock, \$0.0001 par value - 40,000 shares authorized; 24,639 and 29,290 issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	3	3
Class C common stock, \$0.0001 par value - 20,000 shares authorized; none issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	72,379	55,737
Accumulated other comprehensive loss	(57)	—
Accumulated deficit	<u>(30,133)</u>	<u>(8,331)</u>
Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc.	42,194	47,411
Non-controlling interest	<u>44,413</u>	<u>74,156</u>
Total stockholders' equity	<u>86,607</u>	<u>121,567</u>
Total liabilities and stockholders' equity	<u>\$ 108,202</u>	<u>\$ 124,207</u>

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Contract revenue	\$ —	\$ —	\$ —	\$ 2,717
Operating expenses				
Research and development	9,103	11,959	26,221	19,065
General and administrative	7,239	15,822	19,748	21,889
Total operating expenses	<u>\$ 16,342</u>	<u>\$ 27,781</u>	<u>\$ 45,969</u>	<u>\$ 40,954</u>
Loss from operations	(16,342)	(27,781)	(45,969)	(38,237)
Other income (expense), net				
Interest income and other, net	379	13	430	73
Loss on extinguishment of debt	—	(700)	—	(700)
Interest expense and other, net	(352)	(110)	(352)	(467)
Change in estimated fair value of preferred unit warrant	—	(85)	—	(371)
Loss before income taxes	<u>(16,315)</u>	<u>(28,663)</u>	<u>(45,891)</u>	<u>(39,702)</u>
Income tax expense	107	(37)	(111)	(81)
Net loss	<u>\$ (16,208)</u>	<u>\$ (28,700)</u>	<u>\$ (46,002)</u>	<u>\$ (39,783)</u>
Net loss attributable to non-controlling interest	(8,253)	(25,558)	(24,200)	(36,641)
Net loss attributable to Rani Therapeutics Holdings, Inc.	<u>\$ (7,955)</u>	<u>\$ (3,142)</u>	<u>\$ (21,802)</u>	<u>\$ (3,142)</u>
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted	<u>\$ (0.33)</u>	<u>\$ (0.16)</u>	<u>\$ (0.93)</u>	<u>\$ (0.16)</u>
Weighted-average Class A common shares outstanding—basic and diluted	<u>24,468</u>	<u>19,437</u>	<u>23,449</u>	<u>19,437</u>

