UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):
October 24, 2022

Rani Therapeutics Holdings, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-40672**	**86-3114789**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2051 Ringwood Avenue **San Jose, California**	**95131**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (408) 457-3700

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, par value $0.0001 per share	**RANI**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On October 24, 2022, Rani Therapeutics Holdings, Inc. (the "Company") issued a press release providing an update regarding its pipeline and a corporate update. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release dated October 24, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Rani Therapeutics Holdings, Inc.

Date: October 24, 2022

By: /s/ Svai Sanford
Svai Sanford
Chief Financial Officer

Rani Therapeutics Announces New RT-111 Development Program and Provides Corporate Update

- Rani announces 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 -

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

- Initiation of in vivo studies with fully-autonomous RaniPill HC anticipated in 4Q 2022 -

SAN JOSE, Calif., October 24, 2022—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 the preclinical development of RT-111, a RaniPill GO capsule containing an ustekinumab biosimilar, as part of a corporate and pipeline update.

Ustekinumab, approved in the United States as STELARA®, is used for the treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, moderate to severe Crohn's disease, and moderate to severe ulcerative colitis, all of which have large unmet medical needs for oral treatment.

"Ustekinumab has helped thousands of patients with inflammatory autoimmune diseases, but today the treatment requires regular long-term injections. Rani is developing RT-111, an orally administered ustekinumab biosimilar, with the goal of reducing the burden of treatment and improving outcomes for patients. We are increasingly excited about the potential of the RaniPill platform to provide patients with oral replacements to current injectable standards of care, and we expect that RT-111 will be the first of many expansions of our pipeline," said Talat Imran, Chief Executive Officer of Rani.

In the remainder of 2022, Rani anticipates sharing repeat-dose topline data from Part 2 of its Phase 1 study with RT-102, the RaniPill GO containing a proprietary formulation of human parathyroid hormone (PTH) for the potential treatment of osteoporosis. The RaniPill GO has been developed to deliver payloads up to 3mg with high bioavailability. In addition, Rani intends to conduct in vivo studies with a fully-autonomous RaniPill HC, its high-capacity capsule that is intended to enable delivery of payloads up to 20mg with high bioavailability. Looking further ahead, in 2023 Rani intends to initiate a Phase 2 study with RT-102 and to commence Phase 1 studies with three pipeline molecules.

Rani has developed and clinically tested a drug-agnostic oral delivery platform, the RaniPill capsule, which can deliver any drug, including large molecules such as peptides, proteins, and antibodies. Rani is advancing an internal pipeline of oral therapeutics using the RaniPill technology; and intends to complement these programs with partnering activities to maximize the value of the RaniPill capsule. Rani believes that the RaniPill GO and RaniPill HC could enable delivery of most biologics currently on the market via a convenient, oral daily dose.

Pipeline Updates

RT-111

- Rani has begun preclinical development with RT-111, a RaniPill GO capsule containing a biosimilar of STELARA® (ustekinumab).
- STELARA® (ustekinumab) is an interleukin-12 and interleukin-23 antagonist marketed by Janssen Biotech, Inc. with sales of approximately $5.9 billion in the United States and approximately $9.1 billion worldwide in 2021. The latest expiring United States patent for STELARA® (ustekinumab) will expire in September 2023.
- In the United States, there were estimated to be 7 million patients with psoriasis and 3 million patients with Crohn's disease or ulcerative colitis in 2021.

RT-102

- In August 2022, Rani announced positive topline results from Part 1 of its Phase 1 study of RT-102, meeting all of its endpoints while being generally well-tolerated. In the study, RT-102 orally delivered 20µg and 80µg of PTH with 300-400% greater bioavailability than subcutaneous Forteo® (teriparatide) 20µg.
- Rani anticipates announcing topline data from Part 2 of the Phase 1 study of RT-102, which will be the first repeat-dose data of the RaniPill capsule in humans, in the fourth quarter of 2022.

RaniPill HC

- Rani is continuing development of the RaniPill HC, a high-capacity RaniPill capsule capable of delivering drug payloads up to 20mg, 500%-plus higher than the payload capacity of the RaniPill GO.
- Rani intends to conduct in vivo studies with a fully-autonomous RaniPill HC in the fourth quarter of 2022.

Repeat-Dose Studies

- Rani will not be initiating a separate repeat-dose platform study in 2022. Rani incorporated repeat dosing into the design of its Phase 1 study of RT-102 and expects to obtain longer term repeat-dose data in a Phase 2 study of RT-102 planned for 2023.

RT-109

- Following a strategic priority review, Rani has decided not to continue active development of RT-109, a RaniPill capsule containing human growth hormone. Rani remains open to partnering opportunities with respect to RT-109, but intends to focus internal efforts on its other pipeline programs.

Updated Milestone Expectations

- 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, RT-110 and RT-111.

RT-105 is the RaniPill containing an adalimumab biosimilar. RT-110 is the RaniPill containing PTH for hypo-parathyroidism.

Included with this press release, and on the company's website at www.ranitherapeutics.com/pipeline, is an updated pipeline chart with updated milestone expectations.

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 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 Part 2 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 optimizing the formulation of RT-101, expected progress with the RaniPill HC platform, the prospects for expanding Rani's pipeline, the impact of Rani's technology on medical treatment including the ability of RaniPill GO and RaniPill HC to deliver biologics currently on the market, 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, Rani's ability to attract and retain talent, 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," "expect," "could,"

“anticipate,” “intend,” “look forward,” “progress,” “advance,” “potential,” “intend,” “can,” “enable,” “believe,” “will,” “continue” 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.

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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Source: Rani Therapeutics

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