# 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):**
**June 01, 2023**

# 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**<br>**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 1.01 Entry into a Material Definitive Agreement.**

*License and Supply Agreement*

On June 1, 2023, Rani Therapeutics, LLC, an operating subsidiary of Rani Therapeutics Holdings, Inc. ("Rani"), and Celltrion, Inc. ("Celltrion") entered into a License and Supply Agreement (the "License Agreement"). Under the License Agreement, Celltrion grants Rani an exclusive, worldwide, royalty-free license to certain intellectual property to make, use, sell, offer for sale, import and otherwise exploit an orally-administered therapeutic product using Rani's oral delivery technology and Celltrion's adalimumab biosimilar ("Product") and to use certain information to support the manufacture, development and commercialization of Product. Celltrion will provide, and Rani will purchase, supply of adalimumab biosimilar at supply prices set forth in the License Agreement. In accordance with the License Agreement, Rani will obtain adalimumab biosimilar exclusively from Celltrion for the manufacture, development and commercialization of Product, except that Rani has the right to obtain supply from alternative sources under certain circumstances where Celltrion experiences supply disruption.

Rani has sole right to manufacture, develop and commercialize Product worldwide, subject to an exclusive right of first negotiation ("ROFN") granted to Celltrion. Following delivery from Rani to Celltrion of a data package consisting of topline safety information, pharmacokinetic results and device performance, and the raw data related to topline results from a phase 1 clinical trial of Product that meets its primary endpoints ("Data Package"), Celltrion will have thirty (30) days to exercise its ROFN. If Celltrion timely exercises the ROFN, then Celltrion will have an exclusive period of ninety (90) days to negotiate in good faith a definitive agreement with Rani for rights to clinically develop and commercialize Product in territories selected by Celltrion. In the event Celltrion does not timely exercise the ROFN or Celltrion notifies Rani that it does not intend to exercise the ROFN or, after timely exercising the ROFN, notifies Rani that Celltrion withdraws its exercise of the ROFN, or the parties fail to enter into a definitive agreement for the development and commercialization of Product within the exclusive negotiation period, then the ROFN will terminate and Rani will have no further obligations under the License Agreement related to a ROFN. The License Agreement allocates rights between the parties with respect to inventions generated in performance of the License Agreement for the manufacture, development and commercialization of Product. Rani will own all data related to the research, development, manufacture, regulatory activities and commercialization of Product conducted by Rani hereunder.

The License Agreement contains customary representations, warranties and covenants, and mutual indemnification provisions. Under the License Agreement, Rani has a right to terminate for convenience subject to certain notice periods, and subject to certain conditions if terminated prior to completion of a phase 1 trial. Celltrion has a right to terminate if Rani does not achieve certain development milestones, and each party has certain rights to terminate for material breach or safety concerns regarding the adalimumab biosimilar or Product.

The description of the License Agreement contained herein does not purport to be complete and is qualified in its entirety by reference to the complete text of the License Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023.

**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: June 5, 2023

By: /s/ Svai Sanford

Svai Sanford
Chief Financial Officer