UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-40672

RANI THERAPEUTICS HOLDINGS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**86-3114789**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. 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

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 8, 2023, the registrant had 25,531,772 shares of Class A common stock, $0.0001 par value per share, outstanding, 24,116,444 shares of Class B common stock, $0.0001 par value per share, outstanding and no shares of Class C common stock, $0.0001 par value per share, outstanding. Certain holders of units of the registrant's consolidated subsidiary, Rani Therapeutics, LLC, who do not hold shares of the registrant's Class B common stock can exchange their units of Rani Therapeutics, LLC for 1,376,851 shares of the registrant's Class A common stock.

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Unless otherwise stated or the context otherwise requires, the terms "we," "us," and "our," and similar references refer to Rani Therapeutics Holdings, Inc. ("Rani Holdings") and its consolidated subsidiary, Rani Therapeutics, LLC ("Rani LLC") and, prior to December 15, 2022, Rani Management Systems, Inc. ("RMS"). RMS was dissolved as of December 15, 2022.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and consolidated financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, manufacturing costs, regulatory approvals, development and advancement of our oral delivery technology, timing and likelihood of success, potential partnering activities as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," "seek," "aim," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the progress and focus of our current and future clinical trials in the United States and abroad, and the reporting of data from those trials;
- our ability to advance product candidates into and successfully complete clinical trials;
- the beneficial characteristics, safety, efficacy, and therapeutic effects of our product candidates;
- our potential and ability to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved;
- our ability to complete development of the RaniPill HC or any redesign and conduct additional preclinical and clinical studies of the RaniPill HC or any future design of the RaniPill capsule to accommodate target payloads that are larger than the payload capacity of the RaniPill GO capsule currently used for our product candidates;
- our ability to further develop and expand our platform technology;
- our ability to utilize our technology platform to generate and advance additional product candidates;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- our financial performance;
- our plans relating to commercializing our product candidates, if approved;
- our ability to selectively enter into strategic partnership and the expected potential benefits thereof;
- the implementation of our strategic plans for our business and product candidates;
- our ability to continue to scale and optimize our manufacturing processes by expanding our use of automation;
- our estimates of the number of patients in the United States who suffer from the indications we target and the number of patients that will enroll in our clinical trials;
- the size of the market opportunity for our product candidates in each of the indications we target;
- our ability to continue to innovate and expand our intellectual property by developing novel formulations and new applications of the RaniPill capsule;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- the scope of protection we are able to establish and maintain for intellectual property rights, including our technology platform and product candidates;

- the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- our realization of any benefit from our organizational structure, taking into account our obligations under the Tax Receivable Agreement (defined herein) and the impact of any payments required to be made thereunder on our liquidity and financial condition; and
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act").

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions described in the section titled "Risk Factors" and elsewhere in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 22, 2023. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, or otherwise.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

RANI THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except par value)

	June 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 7,552	$ 27,007
Marketable securities	67,054	71,475
Prepaid expenses and other current assets	1,768	2,442
Total current assets	76,374	100,924
Property and equipment, net	5,939	6,038
Operating lease right-of-use asset	1,194	1,065
Total assets	$ 83,507	$ 108,027
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,037	$ 1,460
Accrued expenses and other current liabilities	3,842	2,349
Operating lease liability, current portion	856	1,006
Total current liabilities	5,735	4,815
Operating lease liability, less current portion	338	59
Long-term debt	29,265	29,149
Total liabilities	35,338	34,023
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of June 30, 2023 and December 31, 2022	—	—
Class A common stock, $0.0001 par value - 800,000 shares authorized; 25,517 and 25,295 issued and outstanding as of June 30, 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 June 30, 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 June 30, 2023 and December 31, 2022	—	—
Additional paid-in capital	80,746	75,842
Accumulated other comprehensive loss	(63)	(73)
Accumulated deficit	(56,594)	(38,919)
Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc.	24,094	36,855
Non-controlling interest	24,075	37,149
Total stockholders' equity	48,169	74,004
Total liabilities and stockholders' equity	$ 83,507	$ 108,027

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

RANI THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	11,086	9,528	$ 20,798	$ 17,118
General and administrative	7,208	6,319	14,012	12,509
Total operating expenses	$ 18,294	$ 15,847	$ 34,810	$ 29,627
Loss from operations	(18,294)	(15,847)	(34,810)	(29,627)
Other income (expense), net				
Interest income and other, net	896	35	1,787	50
Interest expense and other, net	(1,266)	—	(2,473)	—
Loss before income taxes	(18,664)	(15,812)	(35,496)	(29,577)
Income tax expense	—	(154)	—	(217)
Net loss	$ (18,664)	$ (15,966)	$ (35,496)	$ (29,794)
Net loss attributable to non-controlling interest	(9,361)	(8,342)	(17,821)	(15,947)
Net loss attributable to Rani Therapeutics Holdings, Inc.	$ (9,303)	$ (7,624)	$ (17,675)	$ (13,847)
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted	$ (0.37)	$ (0.31)	$ (0.70)	$ (0.60)
Weighted-average Class A common shares outstanding—basic and diluted	25,345	24,371	25,293	22,930

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

RANI THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (18,664)	$ (15,966)	$ (35,496)	$ (29,794)
Other comprehensive loss				
Net unrealized (loss) gain on marketable securities	(107)	—	19	—
Comprehensive loss	$ (18,771)	$ (15,966)	$ (35,477)	$ (29,794)
Comprehensive loss attributable to non-controlling interest	(9,415)	(8,342)	(17,811)	(15,947)
Comprehensive loss attributable to Rani Therapeutics Holdings, Inc.	$ (9,356)	$ (7,624)	$ (17,666)	$ (13,847)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

RANI THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands)
(Unaudited)

	Class A Common Stock		Class B Common Stock						
	Shares	Amount	Shares	Amount	Additional Paid In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Non-Controlling Interest	Total Stockholders' Equity
Balance at December 31, 2022	25,295	$ 3	24,116	$ 2	$ 75,842	$ (73)	$ (38,919)	$ 37,149	$ 74,004
Issuance of common stock under employee equity plans, net of shares withheld for tax settlement	81	—	—	—	(124)	—	—	—	(124)
Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC	—	—	—	—	98	—	—	(98)	—
Stock-based compensation	—	—	—	—	2,202	—	—	2,213	4,415
Net loss	—	—	—	—	—	—	(8,372)	(8,460)	(16,832)
Other comprehensive loss	—	—	—	—	—	63	—	63	126
Balance at March 31, 2023	25,376	$ 3	24,116	$ 2	$ 78,018	$ (10)	$ (47,291)	$ 30,867	$ 61,589
Issuance of common stock under employee stock purchase plan	63	—	—	—	219	—	—	—	219
Issuance of common stock under employee equity plans, net of shares withheld for tax settlement	78	—	—	—	(9)	—	—	—	(9)
Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC	—	—	—	—	(54)	—	—	54	—
Equity-based compensation	—	—	—	—	2,572	—	—	2,569	5,141
Net loss	—	—	—	—	—	—	(9,303)	(9,361)	(18,664)
Other comprehensive loss	—	—	—	—	—	(53)	—	(54)	(107)
Balance at June 30, 2023	25,517	$ 3	24,116	$ 2	$ 80,746	$ (63)	$ (56,594)	$ 24,075	$ 48,169

	Class A Common Stock		Class B Common Stock					
	Shares	Amount	Shares	Amount	Additional Paid In Capital	Accumulated Deficit	Non-Controlling Interest	Total Stockholders' Equity
Balance at December 31, 2021	19,712	$ 2	29,290	$ 3	$ 55,737	$ (8,331)	$ 74,156	$ 121,567
Effect of exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC	4,675	—	(4,517)	—	—	—	—	—
Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC	—	—	—	—	10,928	—	(10,928)	—
Equity-based compensation	—	—	—	—	1,268	—	1,637	2,905
Net loss	—	—	—	—	—	(6,223)	(7,605)	(13,828)
Balance at March 31, 2022	24,387	$ 2	24,773	$ 3	$ 67,933	$ (14,554)	$ 57,260	$ 110,644
Forfeiture of restricted stock awards	(3)	—	—	—	(3)	—	(3)	(6)
Effect of exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC	110	—	(110)	—	—	—	—	—
Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC	—	—	—	—	126	—	(126)	—
Equity-based compensation	—	—	—	—	1,930	—	2,052	3,982
Net loss	—	—	—	—	—	(7,624)	(8,342)	(15,966)
Balance at June 30, 2022	24,494	$ 2	24,663	$ 3	$ 69,986	$ (22,178)	$ 50,841	$ 98,654

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

RANI THERAPEUTICS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (35,496)	$ (29,794)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	9,556	6,881
Depreciation and amortization	377	233
Non-cash operating lease expense	520	317
Amortization of debt discount and issuance costs	116	—
Net accretion and amortization of investments in marketable securities	(1,242)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	860	1,330
Accounts payable	(332)	209
Accrued expenses and other current liabilities	1,707	1,453
Operating lease liabilities	(521)	(317)
Net cash used in operating activities	(24,455)	(19,688)
Cash flows from investing activities		
Purchases of marketable securities	(52,505)	—
Proceeds from maturities of marketable securities	58,000	—
Purchases of property and equipment	(583)	(633)
Net cash provided by (used in) investing activities	4,912	(633)
Cash flows from financing activities		
Issuance of common stock under employee stock purchase plan	219	—
Proceeds from employee stock purchase plan	2	49
Tax withholdings paid on behalf of employees for net share settlement	(133)	—
Net cash provided by financing activities	88	49
Net decrease in cash, cash equivalents and restricted cash equivalents	(19,455)	(20,272)
Cash, cash equivalents and restricted cash equivalents, beginning of period	27,507	117,453
Cash, cash equivalents and restricted cash equivalents, end of period	$ 8,052	$ 97,181
Supplemental disclosures of non-cash investing and financing activities		
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 578	$ —
Interest income receivable included in prepaid expenses	$ 186	$ —
Property and equipment purchases included in accounts payable and accrued expenses and other current liabilities	$ 38	$ 340
Exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC	$ —	$ 74,567

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

1. Organization and Nature of Business

Description of Business

Rani Therapeutics Holdings, Inc. (“Rani Holdings”) was formed as a Delaware corporation in April 2021 for the purpose of facilitating an initial public offering (“IPO”) of its Class A common stock, and to facilitate certain organizational transactions and to operate the business of Rani Therapeutics, LLC (“Rani LLC”) and its consolidated subsidiary, Rani Management Services, Inc. (“RMS”). Rani Holdings and its consolidated subsidiaries, Rani LLC and RMS (prior to December 15, 2022), are collectively referred to herein as “Rani” or the “Company.” RMS was dissolved on December 15, 2022.

The Company is a clinical stage biotherapeutics company focusing on advancing technologies to enable the administration of biologics and drugs orally, to provide patients, physicians, and healthcare systems with a convenient alternative to painful injections. The Company is advancing a portfolio of oral therapeutics using its proprietary delivery technology, the RaniPill capsule. The Company is headquartered in San Jose, California and operates in one segment.

Organizational Transactions

In connection with the IPO, the Company was party to the following organizational transactions (the “Organizational Transactions”):

- Amended and restated Rani LLC’s operating agreement (the “Rani LLC Agreement”) to appoint the Company as the sole managing member of Rani LLC and effectuated an exchange of all outstanding (i) convertible preferred units, automatic or net exercised warrants to purchase preferred units and common units, and common units of Rani LLC, into economic nonvoting Class A units (“Class A Units”) and an equal number of voting noneconomic Class B units (“Class B Units”) and (ii) all non-vested incentive units (“Profits Interests”) into Class A Units. In connection with the closing of the IPO, each LLC interest was exchanged 1 for 0.5282 as determined and predicated on the initial public offering price of the Company’s Class A common stock;
- Amended and restated the Company’s certificate of incorporation in July 2021, to provide for the issuance of (i) Class A common stock, each share of which entitles its holders to one vote per share, (ii) Class B common stock, each share of which entitles its holders to 10 votes per share on all matters presented to the Company's stockholders, (iii) Class C common stock, which has no voting rights, except as otherwise required by law and (iv) preferred stock;
- Exchanged 12,047,925 shares of Class A common stock for existing Class A Units of Rani LLC held by certain individuals and entities (the “Former LLC Owners”) on a one-for-one basis;
- Issued 29,290,391 shares of Class B common stock to certain individuals and entities that continued to hold Class A Units in Rani LLC after the IPO (the “Continuing LLC Owners”) in return for an equal amount of Rani LLC Class B Units;
- Entered into a Registration Rights Agreement with certain of the Continuing LLC Owners.

The Continuing LLC Owners are entitled to exchange, subject to the terms of the Rani LLC Agreement, the Class A Units they hold in Rani LLC, together with the shares they hold of the Company Class B common stock (together referred to as a "Paired Interest"), in return for shares of the Company’s Class A common stock on a one-for-one basis provided that, at the Company’s election, the Company has the ability to effect a direct exchange of such Class A common stock or make a cash payment equal to a volume weighted average market price of one share of Class A common stock for each Paired Interest redeemed. Any shares of Class B common stock will be cancelled on a one-for-one basis if, at the election of the Continuing LLC Owners, the Company redeems or exchanges such Paired Interest pursuant to the terms of the Rani LLC Agreement. As of June 30, 2023, certain individuals who continue to own interests in Rani LLC but do not hold shares of the Company’s Class B common stock (“non-corresponding Class A Units”) have the ability to exchange their non-corresponding Class A Units of Rani LLC for 1,387,471 shares of the Company’s Class A common stock.

Liquidity

The Company has incurred recurring losses since its inception, including net losses of $35.5 million for the six months ended June 30, 2023. As of June 30, 2023, the Company had an accumulated deficit of $56.6 million and for the six months ended June 30, 2023 had negative cash flows from operations of $24.5 million. The Company expects to continue to generate operating losses and negative operating cash flows for the foreseeable future as it continues to develop the RaniPill capsule. The Company

expects that its cash, cash equivalents and marketable securities of $74.6 million as of June 30, 2023 will be sufficient to fund its operations through at least twelve months from the date the condensed consolidated financial statements are issued. The Company expects to finance its future operations with its existing cash and through strategic financing opportunities that could include, but are not limited to, future offerings of its equity, such as “at the market offerings” as defined in Rule 415(a)(4) under the Securities Act, collaboration or licensing agreements, or the incurrence of debt. However, there is no guarantee that any of these strategic or financing opportunities will be executed or realized on favorable terms, if at all, and some could be dilutive to existing stockholders and holders of interests in the Company. The Company will not generate any revenue from product sales unless, and until, it successfully completes clinical development and obtains regulatory approval of its product candidates. If the Company obtains regulatory approval for the RaniPill capsule, it expects to incur significant expenses related to developing its internal commercialization capability to support manufacturing, product sales, marketing, and distribution.

The Company’s ability to raise additional capital through either the issuance of equity or debt, is dependent on a number of factors including, but not limited to, the market interest of the Company, which itself is subject to a number of development and business risks and uncertainties, as well as the uncertainty that the Company would be able to raise such additional capital at a price or on terms that are favorable to the Company. Current global economic conditions or other factors could also adversely impact the Company’s ability to access capital when and as needed.

2. Summary of Significant Accounting Policies

Basis of Presentation

These condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). Certain prior period amounts have been reclassified to be consistent with current period presentation.

The Company operates and controls all of the business and affairs of Rani LLC and, through Rani LLC conducts its business. Because the Company manages and operates the business and controls the strategic decisions and day-to-day operations of Rani LLC and also has a substantial financial interest in Rani LLC, the Company consolidates the financial results of Rani LLC, and a portion of its net loss is allocated to the non-controlling interests in Rani LLC held by the Continuing LLC Owners. All intercompany accounts and transactions have been eliminated in consolidation.

Unaudited Interim Condensed Consolidated Financial Statements

The accompanying condensed consolidated financial statements have been prepared in accordance with U.S. GAAP for interim financial information and pursuant to Form 10-Q of Regulation S-X of the Securities and Exchange Commission (“SEC”). Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These unaudited condensed consolidated financial statements include all adjustments necessary to fairly state the financial position and the results of the Company's operations and cash flows for interim periods in accordance with U.S. GAAP. All such adjustments are of a normal, recurring nature. Operating results for the three and six months ended June 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023 or for any future period.

The consolidated balance sheet as of December 31, 2022 included herein was derived from the audited consolidated financial statements as of that date. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. Therefore, these interim condensed consolidated financial statements should be read in conjunction with the 2022 consolidated financial statements and notes included in the Company’s Annual Report on Form 10-K filed with the SEC on March 22, 2023.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities in the Company’s condensed consolidated financial statements and accompanying notes. The Company evaluates its estimates on an ongoing basis. The Company bases its estimates on its historical experience and also on assumptions that we believe are reasonable; however, actual results may differ materially and adversely from these estimates.

Significant Accounting Policies

A description of the Company's significant accounting policies is included in the audited consolidated financial statements within its Annual Report on Form 10-K for the year ended December 31, 2022. Except as noted below, there have been no material changes in the Company's significant accounting policies during the six months ended June 30, 2023.

Concentrations of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company maintains accounts in federally insured financial institutions in excess of federally insured limits. The Company also holds money market funds that are not federally insured. However, management believes the Company is not exposed to significant credit risk due to the financial strength of the depository institutions in which these deposits are held and of the money market funds and other entities in which these investments are made.

Cash, Cash Equivalents and Restricted Cash Equivalents

The following table provides a reconciliation of cash and cash equivalents and restricted cash equivalents reported as a component of prepaid expenses and other current assets on the condensed consolidated balance sheet which, in aggregate, represents the amount reported in the condensed consolidated statements of cash flows for the six months ended June 30, 2023 and 2022:

	Six Months Ended June 30,	
	2023	**2022**
End of Period:		
Cash and cash equivalents	$ 7,552	$ 97,181
Restricted cash equivalents	500	—
Total cash, cash equivalents and restricted cash equivalents	$ 8,052	$ 97,181

Marketable Securities

The Company regularly reviews its investments for declines in fair value below their amortized cost basis to determine whether the impairment is due to credit-related factors or noncredit-related factors. The Company's review includes the creditworthiness of the security issuers, the severity of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that the Company will be required to sell the securities before the recovery of its amortized cost bases. When the Company determines that a portion of the unrealized loss is due to an expected credit loss, the Company recognizes the loss amount in Other income (expense), net, with a corresponding allowance against the carrying value of the security the Company holds. The portion of the unrealized loss related to factors other than credit losses is recognized in Accumulated other comprehensive loss. The Company has made an accounting policy election to not measure an allowance for credit loss for accrued interest receivables and will recognize a credit loss for accrued interest receivables when the loss becomes probable and estimable. As of June 30, 2023, interest income receivable recorded as a component of prepaid expenses and other current assets on the condensed consolidated balance sheet totaled $0.2 million.

Fair Value of Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

As of June 30, 2023 and 2022, the carrying values of current assets and liabilities approximates fair value due to their short-term nature, respectively. The fair value of the Company’s long-term debt approximated its carrying value based on borrowing rates currently available to the Company for debt with similar terms and maturities (Level 2 inputs).

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgement exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value of the instrument.

Tax Receivable Agreement

In August 2021, in connection with the IPO and Organizational Transactions, the Company entered into a tax receivable agreement ("TRA") with certain of the Continuing LLC Owners. The TRA provides that the Company pay to such Continuing LLC Owners 85% of the amount of tax benefits, if any, it is deemed to realize (calculated using certain assumptions) as a result of (i) increases in the tax basis of assets of Rani LLC resulting from (a) any future redemptions or exchanges of Paired Interests or non-corresponding Class A Units of Rani LLC and (b) payments under the TRA and (ii) certain other benefits arising from payments under the TRA (collectively the “Tax Attributes”).

A liability for the payable to parties subject to the TRA, and a reduction to stockholders’ equity, is accrued when (i) an exchange of a Paired Interest or non-corresponding Class A Units of Rani LLC has occurred and (ii) when it is deemed probable that the Tax Attributes associated with the exchange will be used to reduce the Company’s taxable income based on the contractual percentage of the benefit of Tax Attributes that the Company expects to receive over a period of time (Note 12).

Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions and other events and/or circumstances from non-owner sources. Other comprehensive loss represents changes in fair value of the Company's available-for-sale marketable securities.

Net Loss Per Class A Common Share Attributable to Rani Holdings

Basic net loss per Class A common share attributable to Rani Holdings is computed by dividing net loss attributable to the Company by the weighted average number of Class A common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per Class A common share is computed giving effect to all potentially dilutive shares. Diluted net loss per Class A common share for all periods presented is the same as basic loss per share as the inclusion of potentially issuable shares would be antidilutive.

Non-Controlling Interest

Non-controlling interest ("NCI") represents the portion of income or loss, net assets and comprehensive loss of the Company's consolidated subsidiary that is not allocable to Rani Holdings based on the Company's percentage of ownership of Rani LLC.

In August 2021, based on the Organizational Transactions, Rani Holdings became the sole managing member of Rani LLC. As of June 30, 2023, Rani Holdings held approximately 50% of the Class A Units of Rani LLC, and approximately 50% of the outstanding Class A Units of Rani LLC are held by the Continuing LLC Owners. Therefore, the Company reports NCI based on the Class A Units of Rani LLC held by the Continuing LLC Owners on its condensed consolidated balance sheet as of June 30, 2023. Income or loss attributed to the NCI in Rani LLC is based on the Class A Units outstanding during the period for which the income or loss is generated and is presented on the condensed consolidated statements of operations and comprehensive loss.

Future exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC will result in a change in ownership and reduce or increase the amount recorded as NCI and increase or decrease additional paid-in-capital when Rani LLC has positive or negative net assets, respectively. From the date of the Organizational Transactions to June 30, 2023, there were 5,173,947 exchanges of Paired Interests and 158,051 exchanges of non-corresponding Class A Units of Rani LLC for an equal number of shares of the Company's Class A common stock.

3. Cash Equivalents, Restricted Cash Equivalents and Marketable Securities

The following tables summarizes the amortized cost and fair value of the Company's cash equivalents, restricted cash equivalents and marketable securities by major investment category (in thousands):

	As of June 30, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 2,660	$ —	$ —	$ 2,660
U.S. Treasuries	3,992	1	—	3,993
Total cash equivalents	6,652	1	—	6,653
Restricted cash equivalents:				
Money market funds	500	—	—	500
Total cash equivalents and restricted cash equivalents	7,152	1	—	7,153
Marketable securities:				
U.S. Treasuries and agencies	52,339	—	(95)	52,244
Commercial paper	6,934	—	(9)	6,925
Corporate debt securities	7,912	—	(27)	7,885
Total marketable securities	67,185	—	(131)	67,054
Total cash equivalents, restricted cash equivalents and marketable securities	$ 74,337	$ 1	$ (131)	$ 74,207

	As of December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 25,313	$ —	$ —	$ 25,313
Total cash equivalents	25,313	—	—	25,313
Restricted cash equivalents:				
Money market funds	500	—	—	500
Total cash equivalents and restricted cash equivalents	25,813	—	—	25,813
Marketable securities:				
U.S. Treasuries and agencies	36,563	—	(107)	36,456
Commercial paper	26,631	—	—	26,631
Corporate debt securities	6,939	—	(39)	6,900
International government	1,491	—	(3)	1,488
Total marketable securities	71,624	—	(149)	71,475
Total cash equivalents, restricted cash equivalents and marketable securities	$ 97,437	$ —	$ (149)	$ 97,288

As of June 30, 2023, all marketable securities are classified as short-term. The Company regularly reviews its available-for-sale marketable securities in an unrealized loss position and evaluates the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. As of June 30, 2023, the aggregate difference between the amortized cost and fair value of each security in an unrealized loss position was de minimis. Since any provision for expected credit losses for a security held is limited to the amount the fair value is less than its amortized cost, no allowance for expected credit loss was deemed necessary at June 30, 2023.

4. Fair Value Measurements

The following tables presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of inputs used in such measurements (in thousands):

	As of June 30, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 2,660	$ —	$ —	$ 2,660
U.S. Treasuries	3,993	—	—	3,993
Restricted cash equivalents:				
Money market funds	500	—	—	500
Marketable securities				
U.S. Treasuries and agencies	52,244	—	—	52,244
Commercial paper	—	6,925	—	6,925
Corporate debt securities	—	7,885	—	7,885
Total assets	$ 59,397	$ 14,810	$ —	$ 74,207

	As of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 25,313	$ —	$ —	$ 25,313
Restricted cash equivalents:				
Money market funds	500	—	—	500
Marketable securities				
U.S. Treasuries and agencies	36,456	—	—	36,456
Commercial paper	—	26,631	—	26,631
Corporate debt securities	—	6,900	—	6,900
International government	—	1,488	—	1,488
Total assets	$ 62,269	$ 35,019	$ —	$ 97,288

Level 1 and Level 2 financial instruments are comprised of investments in money market funds and fixed-income securities. The Company estimates the fair value of its Level 2 financial instruments by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs.

There were no transfers between Level 1, Level 2 and Level 3 of the fair value hierarchy for any of the periods presented.

5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	June 30, 2023	December 31, 2022
Payroll and related	$ 2,391	$ 394
Accrued preclinical and clinical trial costs	554	1,130
Accrued interest	284	69
Accrued professional fees	82	165
Related party payable	—	53
Other	531	538
Total accrued expenses and other current liabilities	$ 3,842	$ 2,349

6. Related Party Transactions

InCube Labs, LLC (“ICL”) is wholly-owned by the Company’s founder and Chairman and his family. The founder and Chairman is the father of the Company’s Chief Executive Officer. The Company’s Chief Scientific Officer is also the brother of the founder and Chairman and thus uncle of the Company’s Chief Executive Officer.

Services agreements

In June 2021, Rani LLC entered into a service agreement with ICL effective retrospectively to January 1, 2021, and subsequently amended such agreement in March 2022 (as amended, the "Rani LLC-ICL Service Agreement"), pursuant to which Rani LLC and ICL agreed to provide personnel services to the other upon requests. Under the amendment in March 2022, Rani LLC has a right to occupy certain facilities leased by ICL in Milpitas, California and San Antonio, Texas (“Occupancy Services”) for general office, research and development, and light manufacturing. The Rani LLC-ICL Service Agreement has a twelve-month term and will automatically renew for successive twelve-month periods unless terminated; except that the Occupancy Services in Milpitas, California have a term until February 2024, following an extension granted in July 2022, with the potential for one additional annual renewal, subject to approval by the landlord upon a nine months’ notice of renewal prior to the end of the lease term, and the Occupancy Services in San Antonio, Texas continue until either party gives six months’ notice of termination. Except for the Occupancy Services, Rani LLC or ICL may terminate services under the Rani LLC-ICL Service Agreement upon 60 days' notice to the other party. The Rani LLC-ICL Service Agreement specifies the scope of services to be provided as well as the methods for determining the costs of services. Costs are billed or charged on a monthly basis by ICL or Rani LLC, respectively.

In June 2021, RMS entered into a service agreement with ICL (the “RMS-ICL Service Agreement”) effective retrospectively to January 1, 2021, pursuant to which ICL agreed to rent a specified portion of its facility in San Jose, California to RMS. Additionally, RMS and ICL agreed to provide personnel services to the other upon requests based on rates specified in the RMS-ICL Service Agreement. In April 2022, RMS assigned the RMS-ICL Service Agreement to Rani LLC. The RMS-ICL Service Agreement has a twelve-month term and will automatically renew for successive twelve-month periods unless terminated. Rani LLC or ICL may terminate services under the RMS-ICL Service Agreement upon 60 days' notice to the other party, except for occupancy which requires six months’ notice. The RMS-ICL Service Agreement specifies the scope of services to be provided as well as the methods for determining the costs of services. Costs are billed or charged on a monthly basis by ICL or Rani LLC, respectively, as well as allocations of expenses based upon Rani LLC’s utilization of ICL’s facilities and equipment.

The table below details the amounts charged by ICL for services and rent, net of the amount that the Company charged ICL, which is included in the condensed consolidated statements of operations (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ 299	$ 286	$ 609	$ 526
General and administrative	61	53	133	116
Total	$ 360	$ 339	$ 742	$ 642

Prior to April 2022, the Company’s eligible employees were permitted to participate in ICL’s 401(k) Plan (“401(k) Plan”). Participation in the 401(k) Plan was offered for the benefit of the employees, including the Company’s named executive officers, who satisfied certain eligibility requirements. In April 2022, the Company established its own 401(k) Plan, with participation offered for the benefit of the employees, including the Company’s named executive officers, who satisfy certain eligibility requirements.

As of June 30, 2023, all of the Company's facilities are owned or leased by an entity affiliated with the Company’s Chairman (Note 7). The Company pays for the use of these facilities through its services agreements with ICL.

Exclusive License, Intellectual Property and Common Unit Purchase Agreement

In June 2021, ICL and the Company, through Rani LLC, entered into an Amended and Restated Exclusive License Agreement which replaced the 2012 Exclusive License Agreement between ICL and Rani LLC, as amended in 2013, and terminated the 2012 Intellectual Property Agreement between ICL and Rani LLC, as amended in June 2013. Under the Amended and Restated Exclusive License Agreement, the Company has a fully paid, exclusive license under certain scheduled patents related to optional features of the device and certain other scheduled patents to exploit products covered by those patents in the field of oral delivery of sensors, small molecule drugs or biologic drugs including, any peptide, antibody, protein, cell therapy, gene therapy or vaccine. The Company covers patent-related expenses and, after a certain period, the Company will have the right to acquire four specified United States patent families from ICL by making a one-time payment of $0.3 million to ICL for each United States patent family that the

Company desires to acquire, up to $1.0 million in the aggregate. This payment will not become an obligation until the fifth anniversary of the Amended and Restated Exclusive License Agreement. The Amended and Restated Exclusive License Agreement will terminate when there are no remaining valid claims of the patents licensed under the Amended and Restated Exclusive License Agreement. Additionally, the Company may terminate the Amended and Restated Exclusive License Agreement in its entirety or as to any particular licensed patent upon notification to ICL of such intent to terminate.

Non-Exclusive License Agreement between Rani and ICL ("Non-Exclusive License Agreement")

In June 2021, the Company, through Rani LLC, entered into the Non-Exclusive License Agreement with ICL a related party, pursuant to which the Company granted ICL a non-exclusive, fully-paid license under specified patents that were assigned from ICL to the Company. Additionally, the Company agreed not to license these patents to a third party in a specific field outside the field of oral delivery of sensors, small molecule drugs or biologic drugs including, any peptide, antibody, protein, cell therapy, gene therapy or vaccine, if ICL can prove that it or its sublicensee has been in active development of a product covered by such patents in that specific field. ICL may grant sublicenses under this license to third parties only with the Company's prior approval. The Non-Exclusive License Agreement will continue in perpetuity unless earlier terminated.

Intellectual Property Agreement with Mir Imran (the "Mir Agreement")

In June 2021, the Company, through Rani LLC, entered into the Mir Agreement, pursuant to which the Company and Mir Imran agreed that the Company would own all intellectual property conceived (i) using any of the Company's people, equipment, or facilities or (ii) that is within the field of oral delivery of sensors, small molecule drugs or biologic drugs including, any peptide, antibody, protein, cell therapy, gene therapy or vaccine. Neither the Company nor Mir Imran may assign the Mir Agreement to any third party without the prior written consent of the other party. The initial term of the Mir Agreement is three years, which can be extended upon mutual consent of the parties. The Mir Agreement may be terminated by either party for any reason within the initial three-year term upon providing three months' notice to the other party.

Tax Receivable Agreement

Certain parties to the TRA, entered into in August 2021 pursuant to the IPO and Organizational Transactions are related parties of the Company. The TRA provides that the Company pay to such entities and individuals 85% of the amount of tax benefits, if any, it is deemed to realize from exchanges of Paired Interests (Note 2). During the six months ended June 30, 2023 and 2022, these parties to the TRA exchanged zero and 2,309,490 Paired Interests, respectively, that resulted in tax benefits subject to the TRA (Note 12).

Registration Rights Agreement

In connection with the IPO, the Company entered into a Registration Rights Agreement. ICL and its affiliates are parties to this agreement. The Registration Rights Agreement provides certain registration rights whereby, at any time following the IPO and the expiration of any related lock-up period, ICL and its affiliates can require the Company to register under the Securities Act of 1933, as amended (the "Securities Act") shares of Class A common stock issuable to ICL and its affiliates upon, at the Company's election, redemption or exchange of their Paired Interests. The Registration Rights Agreement also provides for piggyback registration rights. In March 2022, certain holders of the Company's Class A common stock considered to be related parties were made parties to the Registration Rights Agreement. As a result of certain stockholders exercising their registration rights under the Registration Rights Agreement, in December 2022, the Company filed a registration statement on Form S-3 to register 6,009,542 shares of Class A common stock of the Company held by certain of its stockholders.

Rani LLC Agreement

The Company operates its business through Rani LLC. In connection with the IPO, the Company and the Continuing LLC Owners, including ICL and its affiliates, entered into the Rani LLC Agreement. The governance of Rani LLC, and the rights and obligations of the holders of LLC Interests, are set forth in the Rani LLC Agreement. As Continuing LLC Owners, ICL and its affiliates are entitled to exchange, subject to the terms of the Rani LLC Agreement, Paired Interests for Class A common stock of the Company; provided that, at the Company's election, the Company may effect a direct exchange of such Class A common stock or make a cash payment equal to a volume weighted average market price of one share of Class A common stock for each Paired Interest redeemed.

During the six months ended June 30, 2023 and 2022, certain parties to the Rani LLC Agreement exchanged zero and 2,309,490 Paired Interests, respectively, for an equal number of shares of the Company's Class A common stock.

7. Leases

The Company pays for the use of its office, laboratory and manufacturing facility in San Jose, California as part of the RMS-ICL Service Agreement. In April 2022, RMS assigned the RMS-ICL Service Agreement to Rani LLC. The RMS-ICL Service Agreement has a twelve-month term and will automatically renew for successive twelve-month periods unless Rani LLC or ICL terminate occupancy under the RMS-ICL Service Agreement upon six months' notice. In January 2023, the Company determined it to be reasonably certain that it would exercise its renewal option for a successive twelve-month period through 2024. The Company accounted for the renewal option as a lease modification that did not result in a separate contract and recognized the additional right-of-use asset and corresponding lease liabilities associated with the Rani LLC-ICL Service Agreement in its condensed consolidated balance sheet as of June 30, 2023.

Under the Rani LLC-ICL Service Agreement amended in March 2022, Rani LLC has a right to occupy certain facilities leased by ICL in Milpitas, California and San Antonio, Texas for general office, research and development, and light manufacturing. The Rani LLC-ICL Service Agreement has a twelve-month term and will automatically renew for successive twelve-month periods unless terminated; except that the Occupancy Services in Milpitas, California have a term until February 2024, following an extension granted in July 2022, with the potential for one additional annual renewal, subject to approval by the landlord upon a nine months' notice of renewal prior to the end of the lease term, and the Occupancy Services in San Antonio, Texas continue until either party gives six months' notice of termination. In July 2022, the Company accounted for the lease extension as a lease modification that did not result in a separate contract and recognized the right-of-use asset and lease liabilities associated with the Rani LLC-ICL Service Agreement in its condensed consolidated balance sheet. As of June 30, 2023, the second renewal option for the facility in Milpitas, California was not deemed reasonably certain to be exercised.

The Company's leases are accounted for as operating leases and require certain fixed payments of real estate taxes and insurance in addition to future minimum lease payments, and certain variable payments of common area maintenance costs and building utilities. Variable lease payments are expensed in the period in which the obligation for those payments is incurred. These variable lease costs are payments that vary in amount beyond the commencement date, for reasons other than passage of time. Short-term lease expense for Occupancy Services in San Antonio, Texas under the Rani LLC-ICL Service Agreement, and variable lease payments are excluded in the total operating lease expense and immaterial for the periods presented.

The weighted average remaining lease term and weighted average discount rate related to the Company's right-of-use assets and operating lease liabilities for its operating leases were as follows:

	June 30,	
	2023	2022
Weighted-average remaining lease term (in years)	1.3	1.5
Weighted-average discount rate	10.4%	5.0%

As of June 30, 2023, the Company expects that its future minimum operating lease payments will become due and payable as follows (in thousands):

Year ending December 31,		
2023 (remaining six months)	$	523
2024		749
Total undiscounted future minimum lease payments	$	1,272
Less: Imputed interest		(78)
Total operating lease liability	$	1,194
Less: Operating lease liability, current portion		856
Operating lease liability, less current portion	$	338

8. Warrants

In August 2022, in conjunction with a loan and security agreement (Note 11), the Company issued warrants to purchase 76,336 shares of the Company's Class A common stock. The warrants are exercisable for a period of five years from the grant date, as may be adjusted for certain anti-dilution adjustments, dividends, stock splits, and reverse stock splits, at an exercise price per share equal to $11.79, which may be net share settled at the option of the holder. As of June 30, 2023, there were 76,336 warrants outstanding.

The warrants were determined to be equity classified Level 3 securities with a fair value totaling $0.5 million, estimated on the date of issuance using the Black-Scholes valuation model which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield. Such assumptions represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

9. Stockholders' Equity

For the six months ended June 30, 2023 and 2022, certain of the Continuing LLC Owners executed an exchange of zero and 4,626,639 Paired Interests, respectively, and zero and 158,051 non-corresponding Class A Units of Rani LLC, respectively, in return for an equal number of shares of the Company's Class A common stock. The corresponding shares of the Company's Class B common stock included in the exchange of Paired Interests were subsequently cancelled and retired pursuant to the terms of the Rani LLC Agreement.

In August 2022, the Company entered into a Controlled Equity Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (collectively the "Agents"), pursuant to which the Company 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 the Company may specify by notice to the Agents, in accordance with the terms and conditions set forth in the Sales Agreement. The potential proceeds from the Sales Agreement are expected to be used for general corporate purposes. As of June 30, 2023, the Company has no sales under the Sales Agreement. In connection with the Sales Agreement, the Company recognized deferred offering costs totaling $0.3 million as a component of prepaid expenses and other current assets in the condensed consolidated balance sheet as of June 30, 2023 which will be offset against proceeds upon a sale under the Sales Agreement within the condensed consolidated statement of changes in stockholders' equity.

10. Commitments and Contingencies

Legal Proceedings

In the ordinary course of business, the Company may be subject to legal proceedings, claims and litigation as the Company operates in an industry susceptible to patent legal claims. The Company accounts for estimated losses with respect to legal proceedings and claims when such losses are probable and estimable. Legal costs associated with these matters are expensed when incurred. The Company is currently involved in several opposition proceedings at the European Patent Office, all of which were asserted against us by Novo Nordisk AS. The ultimate outcome of this matter as a loss is not probable nor is there any amount that is reasonably estimable. However, the outcome of the opposition proceedings could impact the Company's ability to prevent third parties from commercializing in Europe products with characteristics similar to those of the Company's RaniPill technology.

Tax Receivable Agreement

The Company is party to a TRA with certain of the Continuing LLC Owners (Note 2). As of June 30, 2023, the Company has not recorded a liability under the TRA related to the income tax benefits originating from the exchanges of Paired Interest or non-corresponding Class A Units of Rani LLC as it is not probable that the Company will realize such tax benefits. To the extent the Company is able to realize the income tax benefits associated with the exchanges of Paired Interest or non-corresponding Class A Units of Rani LLC subject to the TRA, the TRA payable would range from zero to $22.9 million at June 30, 2023.

The amounts payable under the TRA will vary depending upon a number of factors, including the amount, character, and timing of the taxable income of the Company in the future. Should the Company determine that the payment of the TRA liability becomes probable at a future date based on new information, any changes will be recorded on the Company's condensed consolidated statement of operations and comprehensive loss at that time.

11. Long-Term Debt

In August 2022, the Company entered into a loan and security agreement and related supplement (the "Loan Agreement") with Avenue Venture Opportunities Fund, L.P (the "Lender"). The Loan Agreement provides for term loans (the "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, which was drawn in December 2022. The remaining $15.0 million of Loans ("Tranche 2") is uncommitted and is subject to certain conditions and approval by the Lender. The purpose of the Loans is for general corporate purposes. In exchange for access to this facility, the Company agreed

to issue warrants exercisable into 76,336 shares of the Company's Class A common stock, as may be adjusted for certain anti-dilution adjustments, dividends, stock splits, and reverse stock splits, at an exercise price per share equal to $11.79 (Note 8).

Pursuant to the Loan Agreement, the maturity date for the Loans is August 1, 2026 (the “Maturity Date”). The Loan principal is repayable in equal monthly installments beginning September 2024 extendable to March 2025 under certain conditions. The Loans bear interest at a variable rate per annum equal to the greater of (A) the prime rate, as published by the Wall Street Journal from time to time plus 5.60% or (B) 10.35%. The Loan Agreement is collateralized by substantially all of the Company’s assets, in which the Lender is granted continuing security interests. The Loans includes customary events of default, including instances of a material adverse change in the Company’s operations, which may require prepayment of the outstanding Loans. At June 30, 2023, the effective interest rate on the Loans was 15.34% and there were no events of default during the six months ended June 30, 2023. The Company is also subject to certain covenants. As of June 30, 2023, the Company was in compliance with all applicable covenants under the Loan Agreement.

As of June 30, 2023, future principal payments for the Company’s debt are as follows (in thousands):

Year ending December 31,	
2023 (remaining six months)	$ —
2024	5,000
2025	15,000
2026	10,000
Total principal payments	$ 30,000
Less: amount representing debt discount	(735)
Total long-term debt	$ 29,265

12. Income Taxes

The Company’s effective income tax rate was zero and (0.51)% for the six months ended June 30, 2023 and 2022, respectively. As a result of the exchanges from the date of the Organizational Transactions to June 30, 2023, the Company recorded a $18.7 million deferred tax asset related to income tax benefit associated with the basis of the net assets of Rani LLC. Because of the Company’s history of operating losses, the Company believes that recognition of the deferred tax assets arising from such future income tax benefits is currently not more-likely-than-not to be realized and, accordingly, has recognized a full valuation allowance on its deferred tax assets.

There were no material changes to uncertain tax positions for the six months ended June 30, 2023 and 2022, and the Company does not anticipate material changes within the next twelve months.

13. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per Class A common share attributable to Rani Holdings (in thousands, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Numerator:				
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.	$ (9,303)	$ (7,624)	$ (17,675)	$ (13,847)
Denominator:				
Weighted average Class A common share outstanding—basic and diluted	25,345	24,371	25,293	22,930
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.—basic and diluted	$ (0.37)	$ (0.31)	$ (0.70)	$ (0.60)

The following table shows the total outstanding securities considered anti-dilutive and therefore excluded from the computation of diluted net loss per Class A common share attributable to Rani Holdings (in thousands):

	As of June 30,	
	2023	2022
Paired Interests	24,116	24,664
Stock options	6,414	3,688
Restricted stock units	1,756	970
Non-corresponding Class A Units	1,387	1,387
Shares issuable pursuant to the ESPP	82	30
Warrants	76	—
Restricted stock awards	51	86
	33,882	30,825

Shares of Class B Common Stock do not share in the Company’s earnings and are not participating securities. Accordingly, separate presentation of loss per share of Class B Common Stock under the two-class method has not been provided. The outstanding shares of Class B Common Stock were determined to be anti-dilutive for the six months ended June 30, 2023. Therefore, they are not included in the computation of net loss per Class A common share attributable to Rani Holdings.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following management's discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes and other information included elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the Securities and Exchange Commission ("SEC"). Some of the information contained in this discussion and analysis or set forth elsewhere in this document, includes forward looking statements that involve risks, uncertainties, and assumptions. Our actual results could differ materially from those discussed in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors" in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2022. Please also see the section titled "Forward Looking Statements."

The following discussion contains references to calendar year 2022 and the six months ended June 30, 2023 and 2022, respectively, which represents the condensed consolidated financial results of Rani Therapeutics Holdings, Inc. (the "Company") and its subsidiary, Rani Therapeutics, LLC and, prior to December 15, 2022, Rani Management Systems, Inc., for the year ended December 31, 2022 and the six months ended June 30, 2023 and 2022, respectively. Unless we state otherwise or the context otherwise requires, the terms "we," "us," "our," and "Rani" and similar references refers to the Company and its consolidated subsidiaries.

Overview

We are a clinical-stage biotherapeutics company focusing on advancing technologies to enable the administration of biologics and drugs orally, to provide patients, physicians, and healthcare systems with a convenient alternative to painful injections. We are advancing a portfolio of oral therapeutics using our proprietary delivery technology.

We are developing and clinically testing a drug-agnostic oral delivery platform, the RaniPill capsule, which is designed to deliver a wide variety of drug substances, including large molecules such as peptides, proteins, and antibodies. The current RaniPill capsule, the RaniPill GO, is designed to deliver up to a 3 mg dose of drug with high bioavailability. We are also developing a high-capacity version known as the RaniPill HC, which is in preclinical stage and which is intended to enable delivery of drug payloads up to 20 mg with high bioavailability. The RaniPill GO is optimized to orally deliver a variety of therapeutics, and we are advancing development of the RaniPill HC to address biologics and drugs with higher dosing requirements.

Since our inception in 2012, we have devoted the majority of our resources to research and development, manufacturing automation and scaleup, and establishing our intellectual property portfolio. To date, we have financed our operations primarily through an initial public offering ("IPO"), private placements of Rani LLC preferred units, the issuance of convertible promissory notes, long-term debt, and contract revenue generated from our evaluation agreements.

We do not have any products approved for sale, and we have not yet generated any revenue from sales of a commercial product. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development of the RaniPill capsule, which we expect will take a number of years. Given our stage of development, we have not yet established a commercial organization or distribution capabilities, and we have no experience as a company in marketing drugs or a drug-delivery platform. When, and if, any of our product candidates are approved for commercialization, we plan to develop a commercialization infrastructure or engage commercial sales organizations or distributors for those products in the United States, Europe, Asia, and potentially in certain other key markets. We may also rely on partnerships to provide commercialization infrastructure, including sales, marketing, and commercial distribution.

As is common with biotechnology companies, we rely on third-party suppliers for the supply of raw materials and active pharmaceutical ingredients ("APIs") and drug substances required for the production of our product candidates. In addition, we work with third parties to manufacture and develop biologics and drugs for inclusion in the current RaniPill capsule and RaniPill HC. Design work, prototyping and pilot manufacturing are performed in house, and we have utilized third-party engineering firms to assist with the design of manufacturing lines that support our supply of the current RaniPill capsule and RaniPill HC. Certain of our suppliers of components and materials are single source suppliers. We believe our vertically integrated manufacturing strategy will offer significant advantages, including rapid product iteration, control over our product quality and the ability to rapidly scale our manufacturing capacity. This capability also allows us to develop future generations of products while maintaining the confidentiality of our intellectual property. Our vertically integrated manufacturing strategy will result in material future capital outlays and fixed costs related to constructing and operating a manufacturing facility. We have invested and plan to continue to invest in automated

manufacturing production lines for the current RaniPill capsule and RaniPill HC. Those assets deemed to have an alternative future use have been capitalized as property and equipment while those projects related to our assets determined to not have an alternative future use have been expensed as research and development costs.

Development Update

RT-105

In June 2023, we entered into a License and Supply Agreement with Celltrion, Inc. (“Celltrion”) under which we receive an exclusive license and supply of Celltrion’s adalimumab biosimilar for development and commercialization of RT-105 worldwide, subject to a right of first negotiation for Celltrion following completion of a Phase 1 clinical trial that meets its primary endpoint(s) (the “Celltrion Agreement”). RT-105 is the RaniPill capsule containing an adalimumab biosimlar, which we are developing for the treatment of inflammatory conditions.

Financial Update

In August 2022, we entered into a loan and security agreement and related supplement (the “Loan Agreement”) with Avenue Venture Opportunities Fund, L.P (the “Lender”). The Loan Agreement provides for term loans (the “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, which was drawn in December 2022. The remaining $15.0 million of Loans is uncommitted and is subject to certain conditions and approval by the Lender. The purpose of the Loans is for general corporate purposes. The Loan Agreement also contains various covenants and restrictive provisions. As of June 30, 2023, we were in compliance with all applicable debt covenants under the Loan Agreement and had cash, cash equivalents and marketable securities totaling $74.6 million.

In addition, in August 2022, we entered into a Controlled Equity^{SM} Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (collectively, the “Agents”), pursuant to which we may offer and sell from time to time through the Agents up to $150 million of shares of our Class A common stock, in such share amounts as we may specify by notice to the Agents, in accordance with the terms and conditions set forth in the Sales Agreement (“ATM Sales”). As of June 30, 2023, we had not delivered any placement notices to either of the Agents and there had been no ATM Sales.

Organizational Transactions

The Company was incorporated in April 2021 and formed for the purpose of facilitating an IPO of its Class A common stock, and to facilitate certain organizational transactions (“Organizational Transactions”) and to operate the business of Rani Therapeutics, LLC (“Rani LLC”) and its consolidated subsidiary at such time, Rani Management Services, Inc. (“RMS”). In connection with the IPO, we established a holding company structure with the Company as the holding company and its principal asset being the Class A common units (“Class A Units”) of Rani LLC that it owns. As the sole managing member of Rani LLC, the Company operates and controls all of Rani LLC’s operations, and through Rani LLC, conducts all of Rani LLC’s business and the financial results of Rani LLC and RMS (prior to December 15, 2022) are included in the consolidated financial statements of the Company. RMS was dissolved as of December 15, 2022.

Rani LLC has been, and after the IPO continues to be, treated as a pass-through entity for U.S. federal and state income tax purposes and accordingly has not been subject to U.S. federal or state income tax. The wholly owned subsidiary of Rani LLC, RMS, which was incorporated in 2019 and dissolved in December 2022, was taxed as a corporation for U.S. federal and most applicable state, local income tax and foreign tax purposes. As a result of its ownership of interests in Rani LLC ("LLC Interests"), the Company is subject to U.S. federal, state and local income taxes with respect to its allocable share of any taxable income of Rani LLC and will be taxed at the prevailing corporate tax rates. In addition to tax expenses, we also incur expenses related to our operations and may be required to make payments under the Tax Receivable Agreement with certain of the individuals and entities that continue to hold interests in Rani LLC after the IPO (the "Continuing LLC Owners"). The Continuing LLC Owners are entitled to exchange, subject to the terms of the Rani LLC Agreement, the Class A Units they hold in Rani LLC, together with the shares they hold of our Class B common stock (together referred to as a "Paired Interest"), in return for shares of our Class A common stock on a one-for-one basis provided that, at our election, we may effect a direct exchange of such Class A common stock or make a cash payment equal to a volume weighted average market price of one share of Class A common stock for each Paired Interest redeemed. Any shares of Class B common stock will be cancelled on a one-for-one basis if, at the election of the Continuing LLC Owners, we redeem or exchange such Paired Interest pursuant to the terms of the Rani LLC Agreement. These exchanges and redemptions may result in increases in the tax basis of the assets of Rani LLC that otherwise would not have been available. Increases in tax basis resulting from such exchanges may reduce the amount of income tax that the Company would otherwise be required to pay in the future. This tax basis may also decrease the gains (or increase the losses) on future dispositions of certain assets to the extent tax basis is allocated to those

assets. Due to the uncertainty of various factors, we cannot estimate the likely tax benefits we will realize as a result of exchanges, and the resulting amounts we will likely pay out to the Continuing LLC Owners pursuant to the Tax Receivable Agreement; however, we estimate that such payments may be substantial in the event we are profitable. Certain individuals who continue to own interests in Rani LLC but do not hold shares of the Company's Class B common stock ("non-corresponding Class A Units") have the ability to exchange their non-corresponding Class A Units of Rani LLC for 1,387,471 shares of the Company's Class A common stock.

Components of Results of Operations

Operating Expenses

Our operating expenses consisted of research and development and general and administrative activities.

Research and Development Expense

Research and development expense consists primarily of direct and indirect costs incurred in connection with our research and development activities to develop the RaniPill GO and RaniPill HC. These expenses include:

External expenses, consisting of:

- expenses associated with contract research organizations ("CROs"), for managing and conducting clinical trials;
- expenses associated with laboratory supplies, drug material for clinical trials, developing and manufacturing of the RaniPill GO, RaniPill HC and other materials;
- expenses associated with preclinical studies performed by third parties; and
- expenses associated with consulting, advisors, and other external services.

Internal expenses, consisting of:

- expenses including salaries, bonuses, stock-based compensation and benefits for personnel engaged in the research and development functions;
- expenses associated with service and repair of equipment, equipment depreciation, and allocated facility costs for research and development; and
- other research and development costs related to compliance with quality and regulatory requirements.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid or accrued research and development expenses. Nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered. Until future commercialization is considered probable and the future economic benefit is expected to be realized, we do not capitalize pre-launch inventory costs.

Costs of property and equipment related to scaling-up our manufacturing capacity for clinical trials and to support commercialization are capitalized as property and equipment unless the related asset does not have an alternative future use.

The historical focus of our research and development has been on the RaniPill delivery platform and not tracked costs on a project-by-project basis associated with different drug compounds.

At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete development of the RaniPill GO and RaniPill HC and complete the development of, and obtain regulatory approval for, our product candidates. We expect our research and development expenses to increase significantly in the foreseeable future as we continue to invest in activities related to testing and developing the RaniPill GO and RaniPill HC and the development of our product candidates, as our product candidates advance into later stages of development, as we begin to conduct larger clinical trials, as we seek regulatory approvals for our product candidates upon successful completion of clinical trials, and incur expenses associated with hiring additional personnel to support the research and development efforts. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, the successful development of the RaniPill GO and

RaniPill HC and our product candidates is highly uncertain, and we may never succeed in successfully developing the RaniPill GO and/or RaniPill HC or achieve the development of, and regulatory approval for, our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs (including salaries, bonuses, stock-based compensation, and benefits) for personnel in executive, finance, accounting, legal, corporate and business development, and other administrative functions. General and administrative expenses also include legal fees relating to corporate matters, professional fees paid for accounting, auditing, consulting, tax, and administrative consulting services, insurance costs, travel, and facilities, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We anticipate that our general and administrative expenses will increase significantly in the foreseeable future as additional administrative personnel and services are required to manage and support the development of the RaniPill GO and RaniPill HC and our product candidates. We also anticipate that we will incur increased expenses associated with operating as a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer liability insurance, and investor and public relations.

Other Income (Expense), Net

Other income (expense), net primarily consists of interest income earned on our cash equivalents and marketable securities and interest expense from our long-term debt and amortization of debt discount and issuance costs.

Non-Controlling Interest

Non-controlling interest ("NCI") represents the portion of income or loss, net assets and comprehensive loss of our consolidated subsidiary that is not allocable to the Company based on its percentage of ownership of Rani LLC.

In August 2021, based on the Organizational Transactions, the Company became the sole managing member of Rani LLC. As of June 30, 2023, the Company held approximately 50% of the Class A Units of Rani LLC, and approximately 50% of the outstanding Class A Units of Rani LLC are held by the Continuing LLC Owners. Therefore, we report NCI based on the Class A Units of Rani LLC held by the Continuing LLC Owners on our condensed consolidated balance sheet as of June 30, 2023. Income or loss attributed to the NCI in Rani LLC is based on the Class A Units outstanding during the period for which the income or loss is generated and is presented on the condensed consolidated statements of operations and comprehensive income or loss.

Future exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC will result in a change in ownership and reduce or increase the amount recorded as NCI and increase or decrease additional paid-in-capital when Rani LLC has positive or negative net assets, respectively. From the date of the Organizational Transactions to June 30, 2023, there were 5,173,947 exchanges of Paired Interests and 158,051 exchanges of non-corresponding Class A Units of Rani LLC for an equal number of shares of our Class A common stock.

Tax Receivable Agreement

In August 2021, in connection with the IPO and Organizational Transactions, we entered into a tax receivable agreement ("TRA") with certain of the Continuing LLC Owners. The TRA provides that we pay to such Continuing LLC Owners, 85% of the amount of tax benefits, if any, it is deemed to realize (calculated using certain assumptions) as a result of (i) increases in the tax basis of assets of Rani LLC resulting from (a) any future redemptions or exchanges of Paired Interests or non-corresponding Class A Units of Rani LLC and (b) payments under the TRA and (ii) certain other benefits arising from payments under the TRA (collectively the “Tax Attributes”).

A liability for the payable to parties subject to the TRA, and a reduction to stockholders’ equity, is accrued when (i) an exchange of a Paired Interest or non-corresponding Class A Units of Rani LLC has occurred and (ii) when it is deemed probable that the Tax Attributes associated with the exchange will be used to reduce our taxable income based on the contractual percentage of the benefit of Tax Attributes that we expect to receive over a period of time.

Relationship with InCube Labs, LLC

Services Agreements

In June 2021, Rani LLC entered into a service agreement with InCube Labs, LLC (“ICL”) effective retrospectively to January 1, 2021, and subsequently amended such agreement in March 2022 (as amended, the "Rani LLC-ICL Service Agreement"), pursuant to which Rani LLC and ICL agreed to provide personnel services to the other upon requests. Under the amendment in March 2022, Rani LLC has a right to occupy certain facilities leased by ICL in Milpitas, California and San Antonio, Texas (“Occupancy Services”) for general office, research and development, and light manufacturing. The Rani LLC-ICL Service Agreement has a twelve-month term and will automatically renew for successive twelve-month periods unless terminated; except that the Occupancy Services in Milpitas, California have a term until February 2024, following an extension granted in July 2022, with the potential for one additional annual renewal, subject to approval by the landlord upon a nine months’ notice of renewal prior to the end of the lease term, and the Occupancy Services in San Antonio, Texas continue until either party gives six months’ notice of termination. Except for the Occupancy Services, Rani LLC or ICL may terminate services under the Rani LLC-ICL Service Agreement upon 60 days' notice to the other party. The Rani LLC-ICL Service Agreement specifies the scope of services to be provided as well as the methods for determining the costs of services. Costs are billed or charged on a monthly basis by ICL or Rani LLC, respectively.

In June 2021, RMS entered into a service agreement with ICL (the “RMS-ICL Service Agreement”) effective retrospectively to January 1, 2021, pursuant to which ICL agreed to rent a specified portion of its facility in San Jose, California to RMS. Additionally, RMS and ICL agreed to provide personnel services to the other upon requests based on rates specified in the RMS-ICL Service Agreement. In April 2022, RMS assigned the RMS-ICL Service Agreement to Rani LLC. The RMS-ICL Service Agreement has a twelve-month term and will automatically renew for successive twelve-month periods unless terminated. Rani LLC or ICL may terminate services under the RMS-ICL Service Agreement upon 60 days' notice to the other party, except for occupancy which requires six months’ notice. The RMS-ICL Service Agreement specifies the scope of services to be provided as well as the methods for determining the costs of services. Costs are billed or charged on a monthly basis by ICL or Rani LLC, respectively, as well as allocations of expenses based upon Rani LLC’s utilization of ICL’s facilities and equipment.

The table below details the amounts charged by ICL for services and rent, net of the amount charged to ICL under the RMS-ICL Service Agreement, which is included in the condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ 299	$ 286	$ 609	$ 526
General and administrative	61	53	133	116
Total	$ 360	$ 339	$ 742	$ 642

Prior to April 2022, our eligible employees were permitted to participate in ICL’s 401(k) Plan (“401(k) Plan”). Participation in the 401(k) Plan was offered for the benefit of our employees, including our named executive officers, who satisfied certain eligibility requirements. In April 2022, the Company established its own 401(k) Plan, with participation offered for the benefit of the employees, including the Company’s named executive officers, who satisfy certain eligibility requirements.

As of June 30, 2023, all of our facilities are owned or leased by an entity affiliated with our Chairman. Rani LLC pays for the use of these facilities through our services agreements with ICL.

Exclusive License Agreement

In June 2021, we and ICL entered into an Amended and Restated Exclusive License Agreement which replaces the 2012 Exclusive License Agreement, as amended in 2013, and terminates the Intellectual Property Agreement, as amended in June 2013. Under the Amended and Restated Exclusive License Agreement, we have a fully paid, exclusive license under certain scheduled patents related to optional features of the device and certain other scheduled patents to exploit products covered by those patents in the field of oral delivery of sensors, small molecule drugs or biologic drugs including, any peptide, antibody, protein, cell therapy, gene therapy or vaccine. We will cover patent-related expenses and, after a certain period, we will have the right to acquire four specified United States patent families from ICL by making a one-time payment of $0.3 million to ICL for each United States patent family that we desire to acquire, up to $1.0 million in the aggregate. This payment will not become an obligation until the fifth anniversary of the Amended and Restated Exclusive License Agreement. The Amended and Restated Exclusive License Agreement will terminate when there are no remaining valid claims of the patents licensed under the Amended and Restated Exclusive License Agreement.

Additionally, we may terminate the Amended and Restated Exclusive License Agreement in its entirety or as to any particular licensed patent upon notification to ICL of such intent to terminate.

Non-Exclusive License Agreement between Rani and ICL ("Non-Exclusive License Agreement")

In June 2021, we entered into the Non-Exclusive License Agreement with ICL, pursuant to which we granted ICL a non-exclusive, fully-paid license under specified patents that were assigned from ICL to us. Additionally, we agreed not to license these patents to a third party in a specific field outside the field of oral delivery of sensors, small molecule drugs or biologic drugs including, any peptide, antibody, protein, cell therapy, gene therapy or vaccine, if ICL can prove that it or its sublicensee has been in active development of a product covered by such patents in that specific field. ICL may grant sublicenses under this license to third parties only with our prior approval. The Non-Exclusive License Agreement will continue in perpetuity unless terminated.

Intellectual Property Agreement with Mir Imran (the "Mir Agreement")

In June 2021, we entered into the Mir Agreement, pursuant to which we and Mir Imran agreed that we would own all intellectual property conceived (i) using any of our people, equipment, or facilities or (ii) that is within the field of oral delivery of sensors, small molecule drugs or biologic drugs including, any peptide, antibody, protein, cell therapy, gene therapy or vaccine. Neither us nor Mir Imran may assign the Mir Agreement to any third party without the prior written consent of the other party. The initial term of the Mir Agreement is three years, which can be extended upon mutual consent of the parties. The Mir Agreement may be terminated by either party for any reason within the initial three-year term upon providing three months' notice to the other party.

Tax Receivable Agreement

ICL is party to the TRA, entered into in August 2021 pursuant to the IPO and Organizational Transactions. The TRA provides that we pay to such entities and individuals 85% of the amount of tax benefits, if any, it is deemed to realize from exchanges of Paired Interests. During the six months ended June 30, 2023 and 2022, these parties to the TRA exchanged zero and 2,309,490 Paired Interests, respectively, that resulted in tax benefits subject to the TRA.

Registration Rights Agreement

In connection with the IPO, we entered into a Registration Rights Agreement with the Continuing LLC Owners, including ICL. The Registration Rights Agreement provides the Continuing LLC Owners certain registration rights whereby, at any time following the IPO and the expiration of any related lock-up period, the Continuing LLC Owners can require us to register under the Securities Act shares of Class A common stock issuable to them upon, at our election, redemption or exchange of their LLC Interests. The Registration Rights Agreement also provides for piggyback registration rights for the Continuing LLC Owners. As a result of certain stockholders exercising their registration rights under the Registration Rights Agreement, in December 2022 we filed a registration statement on Form S-3 to register 6,009,542 shares of our Class A common stock held by certain of our stockholders.

Rani LLC Agreement

We operate our business through Rani LLC and, prior to December 15, 2022, its subsidiary, RMS. RMS was dissolved on December 15, 2022. In connection with the IPO, we and the Continuing LLC Owners, including ICL, entered into the Fifth Amended and Restated LLC Agreement of Rani LLC (the "Rani LLC Agreement"). The governance of Rani LLC, and the rights and obligations of the holders of LLC Interests, are set forth in the Rani LLC Agreement. As a Continuing LLC Owner, ICL is entitled to exchange, subject to the terms of the Rani LLC Agreement, Paired Interests for our Class A common stock; provided that, at our election, we may effect a direct exchange of such Class A common stock or make a cash payment equal to a volume weighted average market price of one share of Class A common stock for each Paired Interest redeemed.

During the six months ended June 30, 2023 and 2022, these parties to the Rani LLC Agreement exchanged zero and 2,309,490 Paired Interests, respectively, for the Company's Class A common stock.

Results of Operations

The results of operations presented below should be reviewed in conjunction with the condensed consolidated financial statements and notes included elsewhere in this Quarterly Report on Form 10-Q. For information with respect to recent accounting pronouncements that are of significance or potential significance to us, see "Note 2. Summary of Significant Accounting Policies" in the "Notes to the Unaudited Condensed Consolidated Financial Statements" contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Comparison of the three months ended June 30, 2023 and 2022

The following table summarizes our results of operations (in thousands):

	Three Months Ended June 30,			
	2023	2022	Change	
Operating expenses				
Research and development	$ 11,086	$ 9,528	16.4	%
General and administrative	7,208	6,319	14.1	%
Total operating expenses	$ 18,294	$ 15,847	15.4	%
Loss from operations	(18,294)	(15,847)	15.4	%
Other income (expense), net				
Interest income and other, net	896	35	*	
Interest expense and other, net	(1,266)	—	*	
Loss before income taxes	(18,664)	(15,812)	18.0	%
Income tax expense	—	(154)	*	
Net loss	$ (18,664)	$ (15,966)	16.9	%
Net loss attributable to non-controlling interest	(9,361)	(8,342)	12.2	%
Net loss attributable to Rani Therapeutics Holdings, Inc.	$ (9,303)	$ (7,624)	22.0	%

* Not meaningful

Research and Development Expenses

The following table reflects our research and development costs by nature of expense (in thousands):

	Three Months Ended June 30,	
	2023	2022
Payroll, stock-based compensation and related benefits	$ 7,617	$ 6,206
Facilities, materials and supplies	1,603	1,547
Third-party services	1,764	1,667
Other	102	108
Total	$ 11,086	$ 9,528

Research and development expenses were $11.1 million for the three months ended June 30, 2023, compared to $9.5 million for the three months ended June 30, 2022. The increase was primarily attributed to higher compensation costs of $1.4 million, which includes an increase of $0.2 million in stock-based compensation, due to headcount growth.

General and Administrative Expenses

General and administrative expenses were $7.2 million for the three months ended June 30, 2023, compared to $6.3 million for the three months ended June 30, 2022. The increase was primarily attributed to higher compensation costs of $1.2 million, which includes an increase of $0.9 million in stock-based compensation, due to headcount growth, partially offset by a decrease in third-party services of $0.3 million due to non-recurring public company related costs.

Other Income (Expense), Net

Other expense, net, was $0.4 million for the three months ended June 30, 2023, compared to other income, net, which was de minimis for the three months ended June 30, 2022. The increase was primarily attributed to an increase in interest income of $0.9 million from our investment in marketable securities offset by an increase in interest expense of $1.2 million from our long-term debt.

Comparison of the six months ended June 30, 2023 and 2022

The following table summarizes our results of operations (in thousands):

	Six Months Ended June 30,		
	2023	2022	Change
Operating expenses			
Research and development	$ 20,798	$ 17,118	21.5 %
General and administrative	14,012	12,509	12.0 %
Total operating expenses	$ 34,810	$ 29,627	17.5 %
Loss from operations	(34,810)	(29,627)	17.5 %
Other income (expense), net			
Interest income and other, net	1,787	50	*
Interest expense and other, net	(2,473)	—	*
Loss before income taxes	(35,496)	(29,577)	20.0 %
Income tax expense	—	(217)	*
Net loss	$ (35,496)	$ (29,794)	19.1 %
Net loss attributable to non-controlling interest	(17,821)	(15,947)	11.8 %
Net loss attributable to Rani Therapeutics Holdings, Inc.	$ (17,675)	$ (13,847)	27.6 %

* Not meaningful

Research and Development Expenses

The following table reflects our research and development costs by nature of expense (in thousands):

	Six Months Ended June 30,	
	2023	2022
Payroll, stock-based compensation and related benefits	$ 14,988	$ 11,629
Facilities, materials and supplies	3,052	2,509
Third-party services	2,621	2,734
Other	137	246
Total	$ 20,798	$ 17,118

Research and development expenses were $20.8 million for the six months ended June 30, 2023, compared to $17.1 million for the six months ended June 30, 2022. The increase was primarily attributed to higher compensation costs of $3.4 million, which includes an increase of $0.7 million in stock-based compensation, due to headcount growth, and an increase of $0.5 million in facilities, materials and supplies expense related to preclinical and clinical development activities.

General and Administrative Expenses

General and administrative expenses were $14.0 million for the six months ended June 30, 2023, compared to $12.5 million for the six months ended June 30, 2022. The increase was primarily attributed to higher compensation costs of $2.3 million, which includes an increase of $2.0 million in stock-based compensation, due to headcount growth, partially offset by a decrease in third-party services of $0.8 million due to non-recurring public company related costs.

Other Income (Expense), Net

Other expense, net, was $0.7 million for the six months ended June 30, 2023, compared to other income, net, which was de minimis for the six months ended June 30, 2022. The increase was primarily attributed to an increase in interest income of $1.8 million from our investment in marketable securities offset by an increase in interest expense of $2.4 million from our long-term debt.

Liquidity and Capital Resources

Source of Liquidity

We have not generated any revenue from commercial product sales and have incurred significant operating losses and negative cash flows from operations. We have not yet commercialized any products, and we do not expect to generate revenue from

sales of commercial products for several years, if at all. We anticipate that we will continue to incur net losses for the foreseeable future. Since our inception, we have devoted substantially all of our resources on organizing and staffing our company, business planning, research and development activities, including the RaniPill platform design, drug formulation, preclinical studies, clinical trials, manufacturing automation and scale up, establishing our intellectual property portfolio, and providing general and administrative support for these operations. To date, we have financed our operations primarily through an IPO, private placements of Rani LLC preferred units, the issuance of convertible promissory notes, and long-term debt, as well as contract revenue generated from evaluation agreements.

In August 2022, we entered into the Loan Agreement with the Lender. The Loan Agreement provides for 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, which was drawn in December 2022. The remaining $15.0 million of Loans is uncommitted and is subject to certain conditions and approval by the Lender. The purpose of the Loans is for general corporate purposes. The Loan Agreement also contains various covenants and restrictive provisions. As of June 30, 2023, we were in compliance with all applicable debt covenants under the Loan Agreement and had cash, cash equivalents and marketable securities totaling $74.6 million.

In August 2022, we entered into the Sales Agreement with the Agents, pursuant to which we may offer and sell from time to time through the Agents up to $150.0 million of shares of our Class A common stock in ATM Sales. As of June 30, 2023, we had not delivered any placement notices to either of the Agents and there had been no ATM Sales.

Since our inception, we have incurred significant losses and negative cash flows from operations. Our net losses were $35.5 million and $29.8 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of $56.6 million. We expect to continue to incur significant losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities. Until such time as we can generate sufficient revenue from commercial product sales, if ever, we expect to finance our operations through a combination of equity offerings and debt financings, which may include ATM Sales, or other capital sources, which may include strategic collaborations or other arrangements with third parties. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. If we are unable to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose.

Tax Receivable Agreement

We entered into a Tax Receivable Agreement with certain of the Continuing LLC Owners in August 2021 in connection with the IPO. The Tax Receivable Agreement provides for our payment to certain of the Continuing LLC Owners of 85% of the amount of tax benefits, if any, that we are deemed to realize as a result of any basis adjustments and certain other tax benefits arising from payments under the Tax Receivable Agreement. We will have in effect an election under Section 754 of the Code effective for each taxable year in which a redemption or exchange (including deemed exchange) of LLC Interests for shares of our Class A common stock or cash occurs. These Tax Receivable Agreement payments are not conditioned upon any continued ownership interest in either the Company or Rani LLC by such Continuing LLC Owners. The rights of such Continuing LLC Owners under the Tax Receivable Agreement are assignable to transferees of their LLC Interests (other than us as transferee pursuant to subsequent redemptions (or exchanges) of the transferred LLC Interests). We expect to benefit from the remaining 15% of tax benefits, if any, that we may realize.

As of June 30, 2023, we have not recorded a liability under the TRA related to the income tax benefits originating from the exchanges of Paired Interest or non-corresponding Class A Units of Rani LLC as it is not probable that the Company will realize such tax benefits. To the extent the Company is able to realize the income tax benefits associated with the exchanges of Paired Interest or non-corresponding Class A Units of Rani LLC subject to the TRA, the TRA payable would range from zero to $22.9 million at June 30, 2023.

The amounts payable under the TRA will vary depending upon a number of factors, including the amount, character, and timing of the taxable income of the Company in the future. Should the Company determine that the payment of the TRA liability becomes probable at a future date based on new information, any changes will be recorded on the Company's condensed consolidated statement of operations and comprehensive loss at that time.

Future Funding Requirements

Based on our current operating plan, we estimate that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least twelve months from the date of issuance of these condensed consolidated financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with the development of the RaniPill GO, RaniPill HC and our product candidates and because the extent to which we may enter into strategic collaborations or other arrangements with third parties for development of the RaniPill GO, RaniPill HC and/or our product candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates.

To date, we have not generated any commercial product revenue. We do not expect to generate any commercial product revenue unless and until we obtain regulatory approval and commercialize any of our commercial product candidates, and we do not know when, or if at all, that will occur. We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. Our primary uses of cash are to fund our operations, which consist primarily of research and development expenses related to our programs, manufacturing automation and scaleup, and general and administrative expenses. We expect our expenses to continue to increase in connection with our ongoing activities as we continue to advance the RaniPill GO, RaniPill HC and our product candidates. In addition, we expect to incur additional costs operating as a public company.

We may seek to raise capital through equity offerings or debt financings, which may include ATM Sales, collaboration agreements, or other arrangements with other companies, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our consolidated financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the progress, costs, trial design, results of and timing of our preclinical studies and clinical trials;
- the progress, costs, and results of our research pipeline;
- the willingness of the FDA, or other regulatory authorities to accept data from our clinical trials, as well as data from our completed and planned clinical trials and preclinical studies and other work, as the basis for review and approval of our product candidates or collaborator drugs or biologics paired with the RaniPill GO capsule and/or RaniPill HC for various indications;
- the outcome, costs, and timing of seeking and obtaining FDA and any other regulatory approvals;
- the number and characteristics of product candidates that we pursue;
- our ability to manufacture sufficient quantities of the RaniPill capsules;
- our need to expand our research and development activities;
- the costs associated with manufacturing our product candidates, including establishing commercial supplies and sales, marketing, and distribution capabilities;
- the costs associated with securing and establishing commercial infrastructure;
- the costs of acquiring, licensing, or investing in businesses, product candidates, and technologies;
- our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or other intellectual property rights;
- our need and ability to retain key management and hire scientific, technical, business, and engineering personnel;
- the effect of competing drugs and product candidates and other market developments;
- the timing, receipt, and amount of sales from our potential products, if approved;
- our ability to establish strategic collaborations;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- security breaches, data losses or other disruptions affecting our information systems; and

- the economic and other terms, timing of and success of any collaboration, licensing, or other arrangements which we may enter in the future.

If we raise additional capital through debt financing, we may be subject to covenants that restrict our operations including limitations on our ability to incur liens or additional debt, pay dividends, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us. If we raise funds through collaborations, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials or delay investments in our manufacturing scale-up and automation. In addition, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets globally.

The following table summarizes our cash, cash equivalents and marketable securities:

	June 30, 2023	December 31, 2022
Cash and cash equivalents	$ 7,552	$ 27,007
Marketable securities	67,054	71,475
Total cash, cash equivalents and marketable securities	$ 74,606	$ 98,482

As of June 30, 2023, we had cash, cash equivalents and marketable securities of $74.6 million, compared to $98.5 million as of December 31, 2022. We believe our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated operating requirements for at least the next twelve months following the date of issuance of these condensed consolidated financial statements.

Cash Flows

The following table summarizes our cash flows for the periods presented (in thousands):

	Six Months Ended June 30,	
	2023	2022
Net cash used in operating activities	$ (24,455)	$ (19,688)
Net cash provided by (used in) investing activities	4,912	(633)
Net cash provided by financing activities	88	49
Net decrease in cash, cash equivalents and restricted cash equivalents	$ (19,455)	$ (20,272)

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2023 was $24.5 million, which was primarily attributable to a net loss of $35.5 million, partially offset by stock-based compensation expense of $9.6 million, net accretion and amortization of investments in marketable securities of $1.2 million, and non-cash depreciation and amortization expense of $0.4 million. Additionally, there was an increase in accrued expenses and other current liabilities of $1.7 million and decreases in prepaid expenses and other current assets of $0.9 million and accounts payable of $0.4 million for the six months ended June 30, 2023.

Net cash used in operating activities for the six months ended June 30, 2022 was $19.7 million, which was primarily attributable to a net loss of $29.8 million, partially offset by the equity-based compensation expense of $6.9 million and non-cash operating lease expense of $0.3 million. Additionally there was a decrease of $1.3 million in prepaid expenses and other assets due to amortization of director and officer liability insurance, as a result of becoming a publicly traded company, and an increase in accrued expenses of $1.5 million.

Investing Activities

For the six months ended June 30, 2023, net cash provided by investing activities was $4.9 million consisting of $58.0 million in proceeds from maturities of marketable securities partially offset by $52.5 million and $0.6 million in purchases of marketable securities and property and equipment, respectively.

For the six months ended June 30, 2022, net cash used in investing activities was $0.6 million consisting solely of purchases of property and equipment.

Financing Activities

For the six months ended June 30, 2023 and 2022, there were no significant financing activities.

Contractual Obligations and Other Commitments

Except as discussed below, there have been no material changes to our contractual obligations and other commitments as of June 30, 2023, as compared to those disclosed in our Annual Report on Form 10-K.

The following table summarizes our contractual obligations and commitments as of June 30, 2023 (in thousands):

	As of June 30, 2023		
	Total	Short-term	Long-term
Operating leases (1)	$ 1,194	$ 856	$ 338
Debt obligations (2)	31,650	—	31,650
Total	$ 32,844	$ 856	$ 31,988

(1) Represents operating lease payments. See Note 7 to the condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

(2) Represents long-term debt principal maturities and final payment equal to 5.5% of aggregate amount funded, excluding interest. See Note 11 to the condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

In addition, we enter into agreements in the normal course of business with contract research organizations for clinical trials and with vendors for preclinical studies and other services and products for operating purposes, which are generally cancelable upon written notice.

Critical Accounting Policies and Estimates

This discussion and analysis of financial condition and results of operation is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities as of the date of the financial statements and the reported amounts of expenses during the reporting period. On an ongoing basis, management evaluates its estimates and assumptions. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

For further information on our significant accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 22, 2023.

Recently Adopted Accounting Standards

None.

Other Information

JOBS Act Accounting Election

We are an “emerging growth company” within the meaning of the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). The JOBS Act permits an emerging growth company like us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are electing to use this extended transition period and we will therefore comply with new or revised accounting standards on the earlier of (i) when they apply to private companies; or (ii) when we lose our emerging growth company status. As a result, our financial statements may not be comparable

with companies that comply with public company effective dates for accounting standards. We also rely on other exemptions provided by the JOBS Act, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act unless we cease to be an emerging growth company.

We will remain an emerging growth company until the earliest of (1) December 31, 2026 (the last day of the fiscal year following the fifth anniversary of the closing of our initial public offering), (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion, (3) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which would occur if the market value of our Class A common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year or (4) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(e) and 15(d)-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of June 30, 2023.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during the three months ended June 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost–effective control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 1A. Risk Factors

Other than as described below, management believes that there have been no significant changes to the risk factors associated with our business as compared to those disclosed in Part 1, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022, which is incorporated by reference herein.

Any inability to develop, or difficulties or delays in developing, formulations of drugs for our product candidates could prevent or delay our ability to advance our existing product candidates or develop new product candidates, which could adversely affect our commercial prospects and ability to generate revenues.

We develop microtablets of drugs for use in the RaniPill GO and may need to develop or modify formulations of drugs for use in the RaniPill HC. Drug formulation work is difficult and the outcomes are uncertain. If we are not able to develop a drug formulation suitable for use with our RaniPill capsule, it could prevent, limit or delay our ability to pursue or advance product candidates. Even if we are successful in developing drug formulations of product candidates that are suitable for the RaniPill capsule, such formulations may cause the drug to perform differently than another formulation of the drug and could result in our product candidates having a safety or efficacy profile different or worse than other formulations of the drug. If we are unable to develop, or have difficulties or delays in developing, suitable formulations of drugs for the RaniPill capsule, our ability to develop and commercialize product candidates, to expand use of the RaniPill oral delivery technology and to generate revenues could be adversely affected.

Any difficulties or delays in the commencement or completion, or termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. We are in the early stages of our development efforts and have a limited number of product candidates in early clinical development. Other product candidates are still in the formulation or preclinical stages. While we intend to advance our product candidates into initial and later stages of clinical development, we have not, to date, submitted an IND for any of our product candidates. We will be required to submit applicable equivalent regulatory filings to foreign regulatory authorities to the extent we initiate clinical trials outside of the United States.

We do not know whether our planned clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing with the design or implementation of our clinical trials;
- obtaining regulatory authorizations to commence a trial, or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with contract research organizations (“CROs”) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional volunteers or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of a product candidate or obtaining sufficient quantities of other therapies or active pharmaceutical ingredients for use in clinical trials;

- volunteers failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- volunteers choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- volunteers experiencing severe or unexpected drug-related or device-related adverse effects;
- occurrence of serious adverse events in clinical trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process or product formulation that may be necessary or desired;
- shortages in, or delays in obtaining, raw materials for manufacturing our product candidates or adequately scaling our manufacturing processes and procedures to deliver sufficient quantities for use in our clinical trials;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical protocol or relevant regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or comparable foreign regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

Regulatory authorities may require that filings related to the commencement, continuation or termination of a clinical trial be submitted through specific electronic systems or in a specific manner (e.g. format), which may differ from one jurisdiction to another. We may seek to conduct a clinical trial in multiple jurisdictions in an effort to enroll sufficient numbers of patients or to do so in a timely manner or for other reasons. Meeting the requirements of various regulatory agencies could be costly and any delay in meeting, or inability to meet, the regulatory requirements of different jurisdictions regarding submissions could delay or negatively impact our ability to initiate or complete our clinical trials as planned. For example, the European Medicines Agency maintains an electronic Clinical Trial Information System (CTIS) to support interactions between clinical trial sponsors and regulatory agencies for various European Union member states and European Economic Area countries. Clinical trial sponsors can use the CTIS system to apply for authorization to conduct a clinical trial in one or more of such countries. The CTIS system has experienced certain technical issues delaying or preventing sponsors from submitting clinical trial applications. Any failure or inability by us to submit required regulatory documents for our planned or future clinical trials or any failure or inability to do so in the required manner could delay or prevent us from initiating or completing our planned or future clinical trials when we are otherwise ready or at all.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled participants in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes and data protection regulations, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of

these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition, we work with third parties to manufacture, develop, and supply the drug payloads for inclusion in the RaniPill capsule, a development process that is lengthy and expensive. Some of the active ingredients we are utilizing in our development are used by other sponsors to make biosimilars in the United States, and others are not. We and our third-party manufacturers may discover, even late in the process, that a particular drug payload does not demonstrate the necessary characteristics or is unacceptable to the FDA or other regulatory authorities, and we may be forced to abandon such manufacturing and development efforts for such compound and pursue alternative sourcing, or conduct additional, more involved development work to be able to use such compound, which could have an adverse effect on our operations.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. We may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies or clinical trials to bridge our modified product candidates to earlier versions. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may not be successful in maintaining or obtaining formulation and manufacturing collaborations, and any potential partner may not devote sufficient resources to the formulation and manufacturing of our product candidates or may otherwise fail in formulation and manufacturing efforts, which could adversely affect our ability to develop certain of our product candidates and adversely affect our financial condition and operating results.

In the past, we have entered into evaluation agreements with Takeda and certain other pharmaceutical companies concerning the formulation and manufacture of oral versions of Factor VIII and other molecules. In January 2023, we entered into a License and Supply Agreement with Celltrion, under which we receive supply of ustekinumab biosimilar from Celltrion for RT-111 and Celltrion has a right of first negotiation to obtain development and commercialization rights for RT-111 after completion of a Phase 1 clinical trial that meets its primary endpoint(s). In May 2023, we entered into another License and Supply Agreement with Celltrion, under which we receive supply of adalimumab biosimilar from Celltrion for RT-105 and Celltrion has a right of first negotiation to obtain development and commercialization rights for RT-105 after completion of a Phase 1 clinical trial that meets its primary endpoint(s). If we complete such a clinical trial for RT-111 or RT-105, Celltrion exercises its right of first negotiation, and the parties enter into an agreement granting Celltrion development and commercialization rights, we may be reliant on Celltrion to develop and commercialize the applicable product in certain countries or worldwide.

Future evaluation agreements, supply agreements or collaborations entered into, may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and growth prospects. While we plan to expand our reach by selectively entering into strategic partnerships, we may not be able to enter into such partnerships, and if we do, we may not be able to maintain significant rights or control of future development and commercialization of our product candidates. Accordingly, if we collaborate with a third party for development and commercialization of a product candidate, we may relinquish some or all of the control over the future success of that product candidate to the third party, and that partner may not devote sufficient resources to the formulation and manufacture of our product candidate or may otherwise fail in these efforts, in which event the formulation and manufacture of the product candidate in the collaboration could be delayed or terminated and our business could be substantially harmed.

We believe our product candidates are biologic-device combination products that we anticipate will be regulated under the biologic regulations of the FDA based on their primary mode of action as a biologic. Third-party manufacturers may not be able to comply with the regulatory requirements, known as cGMP, applicable to biologic-device combination products, including applicable provisions of the FDA’s drug and biologics cGMP regulations, device cGMP requirements embodied in the medical device Quality System Regulations ("QSRs"), or similar regulatory requirements outside the United States. Our failure, or the failure of our

third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit any BLA or NDA to the FDA.

In addition, the terms of any potential collaboration or other arrangement that we may establish may not be favorable to us or may not be perceived as favorable, which may negatively impact the price of our Class A common stock. In some cases, we may be responsible for continuing formulation and manufacture of a product candidate under a collaboration, and the payments we receive from our partner may be insufficient to cover the cost of this work or may result in a dispute between the parties. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain, which may be detrimental to the development of our other product candidates.

We are subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our collaboration arrangements to fail. Conflicts may arise between us and partners, such as conflicts concerning the implementation of development plans, efforts and resources dedicated to the product candidate, interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a collaborator could act in its own self-interest, which may be adverse to our interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating sufficient revenue to achieve or maintain profitability:

- reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaboration arrangement;
- actions taken by a partner inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; or
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities.

In addition, the termination of a collaboration may limit our ability to obtain rights to the product or intellectual property developed by our collaborator under terms that would be sufficiently favorable for us to consider further development or investment in the terminated collaboration product candidate, even if it were returned to us.

We may seek to enter into collaborations, licenses and other similar arrangements and may not be successful in doing so, and even if we are, we may not realize the benefits of such relationships.

We may seek to enter into, and have entered into, collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, due to capital costs required to develop or commercialize the product candidate or manufacturing constraints. We may not be successful in our efforts to establish or maintain such collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time consuming and complex. Further, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. Following a strategic transaction or license, we may not achieve an economic benefit that justifies such transaction.

In January 2023, we entered into a License and Supply Agreement with Celltrion, under which Celltrion has a right of first negotiation to obtain development and commercialization rights for RT-111 after completion of a Phase 1 clinical trial that meets its primary endpoint(s). In May 2023, we entered into another License and Supply Agreement with Celltrion, under which we receive supply of adalimumab biosimilar from Celltrion for RT-105 and Celltrion has a right of first negotiation to obtain development and commercialization rights for RT-105 after completion of a Phase 1 clinical trial that meets its primary endpoint(s). Even if we complete such a clinical trial for RT-111 or RT-105, Celltrion may not exercise its right of first negotiation, or if it does exercise such right we may not be able to agree on terms favorable to us or acceptable to us or Celltrion. Accordingly, there can be no assurance that we will complete the required development of RT-111 or RT-105, that Celltrion will exercise its right of first negotiation if we do, or that the parties will enter into an agreement granting Celltrion development and commercialization rights for the applicable product following any such exercise of the right of first negotiation.

Even if we are successful in our efforts to establish a collaboration with Celltrion or collaborations with other third parties, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations that we may enter into in the future, or any delay in entering into collaborations related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

Our European patents are presently being challenged in Europe, and if one or more of such challenges is successful it could encourage such party or other parties to challenge additional patents of ours in Europe or other jurisdictions.

Our patent portfolio includes numerous issued European patents and pending European patent applications directed to various technical aspects of our business. The European Patent Office (EPO) provides for an opposition proceeding that could result in revocation of or amendment to a European patent. We are presently involved in opposition proceedings involving four of our European patents at the EPO, all of which opposition proceedings were asserted against us by Novo Nordisk AS.

The first opposition proceeding involves European Patent No. 2515992, which is generally directed to an ingestible device. In July 2021, the EPO issued a decision resulting in an amendment to the claims of the patent. We subsequently filed a notice of appeal with the EPO Appeal Board and we are awaiting a final decision.

The second opposition proceeding involves European Patent No. 2544668, which is generally directed to a therapeutic agent preparation. In December 2021, the EPO issued a decision resulting in revocation of the patent. We subsequently filed a notice of appeal with the EPO Appeal Board and we are awaiting a final decision.

The third opposition proceeding involves European Patent No. 3461478, which is in the same family as European Patent No. 2515992 noted above. In April 2022, the EPO issued a decision resulting in an amendment to the claims of the patent. We subsequently filed a notice of appeal with the EPO Appeal Board and we are awaiting a final decision.

The fourth opposition proceeding involves European Patent No. 3653223, which is generally directed to a swallowable device. In January 2023, the EPO issued a summons to oral proceedings, which proceedings have been scheduled for October 2023.

While we own numerous issued European patents and pending European patent applications, including several in the same patent families as the four patents noted above and which are not currently the subject of opposition proceedings, there is a risk that one or more of our issued European patents will be revoked, or have its claims amended, through an opposition process. If this were to happen to one of our European patents, the corresponding national patent in each European country in which the European patent was validated would similarly be revoked or have its claims amended. We believe that our current patent portfolio provides us with meaningful protection of the RaniPill technology in Europe even apart from the four European patents which are the subject of the current opposition proceedings. However, if any of the current oppositions results in a revocation or reduction in our patent protection, it could encourage Novo Nordisk As or other parties to seek to invalidate or reduce additional patents in Europe or other jurisdictions. If current or future opposition proceedings result in the revocation or amendment of one or more of our patents that cover important aspects of our technology, it could have a material adverse impact on our ability to commercialize and/or our ability to defend against potential competitors in Europe or the applicable jurisdiction(s).

There is a risk that we may face additional oppositions in Europe as additional European patents are granted.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The following is a list of all exhibits filed or furnished as part of this report:

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant as currently in effect (incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 26, 2021).
3.2	Amended and Restated Bylaws of the Registrant as currently in effect (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 9, 2021).
10.1x*	License and Supply Agreement by and between Rani Therapeutics, LLC and Celltrion, Inc. dated May 26, 2023.
10.2x*+	Employment Agreement, dated May 17, 2023, by and between Rani Therapeutics, LLC and Kate McKinley.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*†	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

\+ Management contract.

† The certifications attached as Exhibit 32.1 which accompanies this Quarterly Report on Form 10-Q, are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of this Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.

x Portions of this exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted material is of the type that the Registrant treats as private or confidential.

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 thereunto duly authorized.

Rani Therapeutics Holdings, Inc.

Date: August 11, 2023

By: /s/ Talat Imran

Talat Imran
Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2023

By: /s/ Svai Sanford

Svai Sanford
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

Portions of this exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted material is of the type that the Registrant treats as private or confidential. Omitted portions are indicated by [*].

License and Supply Agreement

By and Between

Rani Therapeutics, LLC

and

Celltrion, Inc.

Dated

May 26, 2023

CONFIDENTIAL

PREAMBLE

This License and Supply Agreement (this "*Agreement*"), effective as of May 26, 2023 (the "*Effective Date*"), is by and between Rani Therapeutics, LLC, a California limited liability company having an address at 2051 Ringwood Ave., San Jose, California 95131, USA ("*Rani*"), and Celltrion, Inc., having an address at 23, Academy-ro, Yeonsu-gu, Incheon, 22014, Republic of Korea ("*Celltrion*"). Rani and Celltrion are sometimes referred to herein individually as a "*Party*" and collectively as the "*Parties*".

RECITALS

WHEREAS, Celltrion is a biopharmaceutical company that develops, manufactures and commercializes therapeutics, and is developing or has developed a biosimilar of adalimumab;

WHEREAS, Rani is a biopharmaceutical company that develops, manufactures and may in the future commercialize therapeutics using its oral delivery technology;

WHEREAS, Rani desires to develop and commercialize Celltrion's adalimumab biosimilar using its oral delivery technology, and Celltrion is willing to enable Rani to do so, on the terms and conditions set forth in this Agreement;

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, the Parties hereto agree as follows:

1. DEFINITIONS

1.1. "*Affiliate*" means, with respect to a Party, any Person which controls, is controlled by or is under common control with such Party. For purposes of this definition only, "control" means the actual power, either directly or indirectly through one or more intermediaries, to direct or cause the direction of the management and policies of such Person, whether by the ownership of 50% or more (or if less than 50%, the maximum ownership interest permitted by applicable Law) of the securities entitled to be voted generally or in the election of directors of such Person, or by contract or otherwise. For the avoidance of doubt, specifically with regards to Section 6.5 (Commercial Supply) of this Agreement, [*] shall be considered an Affiliate of Celltrion as it relates [*].

1.2. "*Agreement*" has the meaning set forth in the Preamble.

1.3. "*Alliance Managers*" has the meaning set forth in Section 3.7 (Alliance Managers).

1.4. "*Alternate Supply*" has the meaning set forth in Section 6.9 (Supply Continuity).

1.5. "*Business Day*" means a day that is not a Saturday, a Sunday or a day on which banking institutions in New York, New York, USA, or Seoul, South Korea, are authorized by applicable Law to remain closed.

1.6. "*Celltrion*" has the meaning set forth in the Preamble.

1.7. "*Celltrion Indemnitees*" has the meaning set forth in Section 12.1.1 (Rani Indemnity).

1.8. "*Celltrion National Core Technology*" means the Common Technical Document (as defined by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)) in its entirety, not discrete portions, related to the development and manufacture of Drug, and such other types of documents and/or information as may be legally defined as national core technology by the Korean government from time to time after the Effective Date.

1.9. "*cGMP*" or "*current Good Manufacturing Practices*" means current Good Manufacturing Practices as defined in the United States Code of Federal Regulations.

1.10. "*Claims*" has the meaning set forth in Section 12.1.1 (Rani Indemnity).

1.11. *"Commercial Supply Agreement"* has the meaning set forth in Section 6.5 (Commercial Supply).

1.12. *"Confidential Information"* shall mean all written, visual, oral or electronic data or information, both technical and non-technical, relating to Disclosing Party's (as defined below) business, products, processes, techniques, research, development, inventions, testing procedures, marketing, financing, or the like, that are disclosed under this Agreement to Receiving Party (as defined below) by Disclosing Party. Confidential Information shall include, without limitation, know-how, pre-clinical data and results, clinical protocols, clinical research results, toxicity and hazard data, assay standards, methods and related information, manufacturing processes and techniques (including, but not necessarily limited to, "Celltrion [*] Technology" as defined in Section 9.7 below), formulae, flow sheets, technical plans, chemical synthesis routes, process schematics, operational details, historical production data, anecdotal process experience, patents, patent applications, technical specifications, research and development plans, preclinical lead profile contents, regulatory approval timeline, sales forecast, business plans, product and market descriptions, sales, cost and promotional expenditure data, plans and projections. For clarity, Confidential Information of a Party will include all information and materials disclosed by such Party or its designee that (a) is marked as "Confidential," "Proprietary" or with similar designation at the time of disclosure or (b) by its nature can reasonably be expected to be considered Confidential Information. Confidential Information shall not include information which falls within the exceptions of clauses (a) through (d) of Section 2 of the Confidentiality Agreement.

1.13. *"Confidentiality Agreement"* has the meaning set forth in Section 9.1 (Confidentiality).

1.14. *"Contract Interest Rate"* means [*].

1.15. *"Control"* means, with respect to any Information or intellectual property, that the applicable Party or any of its Affiliates owns or has a license to such Information or intellectual property and has the ability to grant to the other Party access to and a license or sublicense (as applicable) under such Information or intellectual property as set forth herein without violating the terms of any agreement with any Third Party as of the time such Party would first be required hereunder to grant such access and license or sublicense.

1.16. "*Disclosing Party*" shall mean a Party that discloses Confidential Information to the other Party under this Agreement.

1.17. *"Dollars"* or *"$"* means U.S. Dollars.

1.18. *"Drug"* means the adalimumab biosimilar being developed by Celltrion which has been approved by the European Medicines Agency under the brand name Yuflyma® and is referred to as CT-P17.

1.19. *"Drug Product"* or *"DP"* means the Drug supplied to Rani by Celltrion as drug product in the form or presentation as the Parties may mutually agree.

1.20. "*Drug Substance*" or "*DS*" means the active pharmaceutical ingredient and excipients used in the manufacture of the Drug, supplied to Rani by Celltrion in the form and presentation set forth in Appendix A (Supply Price Schedule) (or such other form or presentation as the Parties may mutually agree).

1.21. *"FDA"* means the U.S. Food and Drug Administration, and any successor agency thereto.

1.22. *"Force Majeure"* has the meaning set forth in Section 14.7 (Force Majeure).

1.23. *"FTE"* means the equivalent of the work of one employee full time for the applicable period of time and employee grade level provided in the FTE Rate Schedule attached hereto as Appendix B.

1.24. *"FTE Rate"* means the hourly rate for FTE time, increasing on January 1 each year by [*] of the then-current FTE Rate, beginning on January 1, 2024. The FTE Rate is an hourly rate as set forth in the FTE Rate Schedule attached to this Agreement as Appendix B. Overtime, and work on weekends, holidays and the like will not be counted with any multiplier (e.g., time-and-a-half or double time) toward the number of hours or rate used to calculate the FTE contribution.

1.25. *"Governmental Authority"* means any government administrative agency, commission or other governmental authority, body or instrumentality, or any federal, state, local, domestic or foreign governmental regulatory body.

1.26. *"IND"* means, with respect to the United States, an Investigational New Drug Application as defined in applicable regulations promulgated by the FDA and filed with the FDA for human clinical testing of a drug or, with respect any jurisdiction other than the United States, an equivalent filing thereof.

1.27. *"Indemnified Party"* has the meaning set forth in Section 12.2 (Claim for Indemnification).

1.28. *"Indemnifying Party"* has the meaning set forth in Section 12.2 (Claim for Indemnification).

1.29. *"Information"* means all tangible and intangible techniques, information, technology, practices, trade secrets, inventions (whether patentable or not), methods, knowledge, know-how, conclusions, skill, experience, test data and results (including pharmacological, toxicological and clinical test data and results), analytical and quality control data, results or descriptions, software and algorithms. *"Information"* excludes tangible materials, including biological compounds, chemical compounds and reagents.

1.30. *"Initial Supply"* has the meaning set forth in Section 6.2 (Initial Supply).

1.31. *"Initiation"* of a clinical trial or to *"Initiate"* a clinical trial means the first dosing of a human subject with Product in such trial.

1.32. *"Joint Steering Committee"* or *"JSC"* has the meaning set forth in Section 2.1 (Joint Steering Committee).

1.33. *"Law"* means, individually and collectively, any and all laws, ordinances, rules, directives, administrative circulars and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction.

1.34. *"Licensed Information"* means all Information in Celltrion's Control, as of the Effective Date or thereafter during the Term, including without limitation information in the investigational brochure for Drug, information in Regulatory Filings, information related to Drug manufacturing or the Chemistry, Manufacturing and Controls section (or the equivalent) of Regulatory Filings, safety and pharmacovigilance data and other information, related to Drug and reasonably necessary for the manufacture, development and/or commercialization of Product, including without limitation the preparation of Regulatory Filings and seeking to obtain Regulatory Approvals for Product.

1.35. *"Licensed IP"* means all Licensed Patents, Licensed Know-How and other intellectual property in Celltrion's Control, as of the Effective Date or thereafter during the Term, (i) relating to Drug, including without limitation methods of use thereof, or (ii) that is necessary or useful for the development (including regulatory activities), manufacture and/or commercialization of Product in the Territory.

1.36. *"Licensed Know-How"* means Information in Celltrion's Control, as of the Effective Date or thereafter during the Term, that is necessary or useful for the development (including regulatory activities), manufacture and/or commercialization of Product in the Territory. Licensed Know-How will include Licensed Information.

1.37. *"Licensed Patents"* means all Patents in Celltrion's Control, as of the Effective Date or thereafter during the Term, that (i) would (absent the licenses granted herein) be infringed by the use, sale, offer for sale, importation or other exploitation of Product in the Territory or (ii) would be necessary or useful for the development (including regulatory activities), manufacture and/or commercialization of Product in the Territory. For purposes of determining whether a patent application falls within clause (i) of this definition, a patent application shall be considered "infringed" if its pending claims would be infringed if issued as then currently set forth in the patent application.

1.38. *"Losses"* has the meaning set forth in Section 12.1.1 (Rani Indemnity).

1.39. *"Notice"* has the meaning set forth in Section 6.4.4 (Non-Conforming DP/DS).

1.40. "*Order*" has the meaning set forth in Section 6.3.2 (Orders).

1.41. *"Order Date"* means the date Rani places the Order for Initial Supply pursuant to Section 6.2 (Initial Supply).

1.42. *"Party"* or *"Parties"* has the meaning set forth in the Preamble.

1.43. *"Patent"* means any of the following, whether existing now or in the future, anywhere in the world: (i) any patents and patent applications (including provisional applications); (ii) any patent applications filed either from such patents or patent applications (including provisional applications) or from an application claiming priority from either of these, including continuations, continuations-in-part, divisionals, converted provisionals, continued prosecution applications, and substitute applications; (iii) any patents issued based on or claiming priority to any such patent applications in (i) and (ii); (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including adjustments, revalidations, renewals, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications in (i), (ii) and (iii); and (v) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patents of addition to any of such foregoing patents or patent applications.

1.44. *"Person"* means an individual, corporation, partnership, limited liability company, limited partnership, trust, business trust, association, joint stock company, joint venture, pool, syndicate, "group" as defined in Section 13(d)(3) of the U.S. Securities Exchange Act of 1934, as amended, sole proprietorship, unincorporated organization, Governmental Authority or any other form of entity not specifically listed herein.

1.45. *"Phase 1 Data"* has the meaning set forth in Section 5.1 (Right of First Negotiation).

1.46. *"Phase 1 Trial"* means, with respect to the United States, any human clinical trial, the principal purpose of which is preliminary determination of safety in healthy individuals or patients as required under 21 C.F.R. §312.21(a), or, with respect to a jurisdiction other than the United States, an equivalent clinical study.

1.47. *"Phase 2 Trial"* means a human clinical trial on sufficient numbers of patients that is designed to establish the safety and preliminary efficacy of a drug for its intended use, and that satisfies the requirements of 21 CFR 312.21(b) (or its successor regulation), or, with respect to a jurisdiction other than the United States, an equivalent clinical study.

1.48. *"Phase 3 Trial"* means a human clinical trial of sufficient numbers of patients that, if the defined end-points are met, is intended to be a pivotal trial for obtaining Regulatory Approval or otherwise intended to supplement existing data on the drug and thereby establish that a drug is sufficiently safe and efficacious for its intended use for the purposes of obtaining Regulatory Approval, and that satisfies the requirements of 21 CFR 312.21(c), or, with respect to a jurisdiction other than the United States, an equivalent clinical study.

1.49. *"Product"* means an orally-administered therapeutic product using Rani Oral Delivery Technology and containing adalimumab as the sole therapeutic agent.

1.50. *"Program Data"* has the meaning set forth in Section 8.5 (Program Data).

1.51. *"Program Inventions"* means inventions generated in performance of this Agreement for the manufacture, development and commercialization of Product.

1.52. "*Quality Agreement*" means a Quality Agreement entered into between the Parties related to the manufacture and supply of Drug Product and/or Drug Substance, as contemplated by Section 6.6 (Quality Agreement).

1.53. *"Rani"* has the meaning set forth in the Preamble.

1.54. *"Rani Indemnitees"* has the meaning set forth in Section 12.1.2 (Celltrion Indemnity).

1.55. *"Rani Oral Delivery Technology"* means oral delivery technology Controlled by Rani or its Affiliates, including the RaniPill™ capsule devices (including the RaniPill HC) for the oral delivery of therapeutic molecules, microtablet formulation technology, and any improvements thereto.

1.56. *"Rani Territory"* means the entire world other than the ROFN Territory.

1.57. "*Receiving Party*" shall mean a Party that receives Confidential Information from the other Party under this Agreement.

1.58. *"Regulatory Approval"* means, with respect to a given therapeutic product, the product-specific approvals, licenses, permits, certifications, registrations or authorizations from Governmental Authorities necessary under applicable Law for the commercial distribution, manufacture, marketing and sale of such product in a country or some or all of an extra-national territory.

1.59. *"Regulatory Filing"* means a filing with any Governmental Authority with respect to the development, manufacture, marketing, commercialization or reimbursement of a therapeutic product.

1.60. *"ROFN"* means the right of first negotiation as set forth in Section 5.1 (Right of First Negotiation).

1.61. *"ROFN Exercise Date"* means the date on which Celltrion has delivered to Rani a ROFN Exercise Notice in accordance with Section 5.1 (Right of First Negotiation).

1.62. *"ROFN Exercise Notice"* has the meaning set forth in Section 5.1 (Right of First Negotiation).

1.63. *"ROFN Exercise Period"* has the meaning set forth in Section 5.1 (Right of First Negotiation) and, subject to Section 5.5 (End of ROFN), will expire upon the earlier of (i) the end of thirty (30) days after receipt by Celltrion of the Phase 1 Data, (ii) the ROFN Exercise Date and (iii) the date this Agreement is terminated.

1.64. *"ROFN Negotiation Period"* has the meaning set forth in Section 5.3 (Negotiation Period) and, subject to Section 5.5 (End of ROFN), will expire upon the earlier of (i) the end of ninety (90) days after the ROFN Exercise Date, (ii) the date the Parties enter into a definitive agreement under Section 5.4 (Definitive Agreement) and (iii) the date this Agreement is terminated.

1.65. *"ROFN Territory"* has the meaning set forth in Section 5.1 (Right of First Negotiation).

1.66. "*Routine In-Person Audit*" has the meaning set forth in Section 6.7 (Rani Inspections).

1.67. "*Specifications*" means the product specifications and the manufacturing process approved by the European Medicines Agency (EMA), unless mutually agreed otherwise by the Parties hereunder.

1.68. "*Stage 1 Supply*" means supply of Drug Product for use in preclinical testing and/or Phase 1 Trials.

1.69. "*Stage 2 Supply*" means supply of Drug Substance for use in, or to support, Phase 2 Trials, Phase 3 Trials and/or late-stage pre-approval activities to support Regulatory Approval of Product.

1.70. "*Stage 3 Supply*" means supply of Drug Substance for use in commercial Product after receipt of Regulatory Approval therefor.

1.71. *"Taxes"* means any tax, excise or duty, other than taxes upon income.

1.72. *"Term"* means the period beginning on the Effective Date and ending upon the termination of this Agreement pursuant to Article 13 (Term and Termination).

1.73. *"Territory"* means the entire world, which is divided into the ROFN Territory and the Rani Territory as set forth in Sections 5.1 and 5.3, respectively.

1.74. *"Third Party"* means any entity other than a Party or an Affiliate of a Party.

1.75. *"United States"* or *"US"* means the United States of America, including its territories and possessions (including the District of Columbia and Puerto Rico).

2. GOVERNANCE

2.1. Joint Steering Committee. Promptly but not later than sixty (60) days following the Effective Date, the Parties will establish a joint steering committee (the *"Joint Steering Committee"* or *"JSC"*) consisting of an equal number of representatives from each Party, in order to (i) facilitate information-sharing regarding the conduct and progress of activities by each Party under the Agreement or Quality Agreement and (ii) resolution of matters that may arise regarding the execution of the Parties' rights and responsibilities under this Agreement

or the Quality Agreement. The JSC will consist of the Alliance Managers and such other employees of the Parties as mutually agreed. The JSC will meet quarterly, or such other frequency as may be mutually agreed by the Parties. The JSC will have no authority to amend, modify or waive compliance with this Agreement or to create new obligations for a Party not specified in this Agreement.

2.2. Alliance Managers. Promptly but not later than sixty (60) days following the Effective Date, each Party will appoint one or more representatives to act as its respective alliance manager(s) (each, an *"Alliance Manager"*). Each Party may replace its respective Alliance Manager(s) at any time upon written notice to the other in accordance with this Agreement. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager. The Alliance Managers will facilitate interactions between the Parties and will serve as a designated point of contact for communication, raising issues or disputes, and planning and coordinating Party interactions, such as JSC meetings.

3. GRANT OF LICENSE

3.1. License to Rani. Celltrion hereby grants to Rani, during the Term, effective as of the Effective Date, an exclusive (even as to Celltrion and its Affiliates), worldwide, royalty-free license under Licensed IP solely (a) to make, have made, use, sell, offer for sale, import and otherwise exploit Product, and (b) to reference and use Licensed Information to support the manufacture, development and commercialization of Product, including use in Regulatory Filings for Product. Rani shall require Celltrion's prior written consent to sublicense the rights granted in this Section 3.1 (License to Rani) to Third Parties prior to the end of the ROFN Exercise Period or, if the ROFN is validly exercised, prior to the end of the ROFN Negotiation Period; except that Rani may sublicense through multiple tiers without consent (i) to subcontractors or vendors to perform work for Rani's development of the Product, and (ii) after the end of the ROFN Exercise Period or, if the ROFN is validly exercised, after the end of the ROFN Negotiation Period, to Third Parties.

3.2. Licensed Information. Upon request of Rani, Celltrion will promptly cooperate to provide to Rani all Licensed Information reasonably requested and will provide Rani with letters of authorization (i.e., a right of reference) to any requested Regulatory Filings or Regulatory Approvals related to Drug (e.g., IND, biologics license application or new drug application) that are reasonably necessary for Rani's development, manufacture or commercialization of Product.

3.3. Retained Rights and Limitations. No rights to either Party's Patents or other proprietary rights are granted pursuant to this Agreement except as expressly set forth herein, and all other rights are reserved. For the avoidance of doubt, the license granted in Section 3.1 (License to Rani) does not restrict Celltrion from supplying and commercializing Drug for any product that is not Product, and furthermore the exclusivity granted in Section 3.1 is only limited to the Product and Celltrion shall be free to offer the Licensed IP for any purposes (including, but not necessarily limited to, licensing) for any product that is not Product.

4. ROLES AND RESPONSIBILITIES

4.1. Development, Manufacture and Commercialization of Product. Rani has sole right to manufacture, develop and commercialize Product (excluding DP and/or DS on its own) worldwide, subject to the ROFN and Celltrion's rights and responsibilities that may result from exercise thereof. Subject to the ROFN, Rani has the right to partner or sublicense its rights hereunder to Third Parties or to engage Third-Party contractors to perform its responsibilities, including without limitation contract research organizations, contract manufacturing organizations and contract sales organizations.

4.2. Supply of DP and/or DS. Celltrion will supply DP and/or DS for Product as set forth in Article 6 (Manufacture and Supply).

4.3. Regulatory Matters.

4.3.1. *Regulatory Responsibilities*. Rani will be responsible for all regulatory activities related to Product, including preparing, submitting and maintaining all Regulatory Filings and Regulatory Approvals for Product and interacting with Governmental Authorities with respect to Product ("*Regulatory Activities*"). Upon reasonable request of Rani, Celltrion will provide to Rani Licensed Information

in support of the Regulatory Activities, and cooperation reasonably requested by Rani in responding to Governmental Authorities regarding matters related to or involving Drug, or DP and/or DS, including without limitation responding to regulatory questions, and facilitating regulatory inspections as set forth in Section 4.3.3 (Inspections).

4.3.2. *Regulatory Meetings.* Rani will be responsible for meetings and communications with Governmental Authorities with respect to Product. Celltrion will not contact or interact with Governmental Authorities with respect to Product unless requested by a Governmental Authority or Rani. If Celltrion is contacted by a Governmental Authority with respect to Product, Celltrion will promptly notify Rani thereof and coordinate with Rani with respect to any response. Rani will have the right to participate in and/or attend scheduled meetings between Celltrion and the applicable Governmental Authority with respect to Product, to the extent not prohibited by such Governmental Authority. Celltrion will inform Rani of any unscheduled teleconferences and meetings with Governmental Authorities with respect to the Product reasonably promptly after they occur.

4.3.3. *Inspections.* Each Party will promptly notify the other Party if it receives notice from a Governmental Authority that it requests or requires to conduct an inspection of Celltrion's manufacturing facilities or a review of Celltrion's batch records or other records with respect to Drug Product and/or Drug Substance in connection with Product. In such event, Celltrion agrees to reasonably cooperate with Rani and to allow such Governmental Authority to inspect such manufacturing facilities and/or review such records to the extent reasonably requested or required. The Parties will keep each other informed as to the date(s) and other relevant information related to such inspection. [*] For clarity, this provision relates solely to inspections specifically related to Product, and not general inspections by Governmental Authorities.

4.4. Safety Reporting. Both Parties will reasonably cooperate with each other regarding pharmacovigilance matters to the extent reasonably required to enable the other Party to comply with applicable Law. From and after the Effective Date, Rani will be responsible for reporting to the relevant Governmental Authorities all adverse events with respect to the Product, to the extent required by and in accordance with Law; and Celltrion will be responsible for reporting to the relevant Governmental Authorities all adverse events with respect to Drug, to the extent required by and in accordance with Law.

4.5. Cooperation Generally. The Parties will provide each other with any cooperation reasonably requested by the other to carry out the purpose and intent of this Agreement, including without limitation with respect to development, manufacturing, and regulatory matters related to Product.

5. RIGHT OF FIRST NEGOTIATION

5.1. Right of First Negotiation. Rani grants to Celltrion an exclusive right of first negotiation ("*ROFN*") for the clinical development and commercialization of Product worldwide. Following completion of the first Phase 1 Trial of Product that meets its primary endpoint(s), Rani will provide to Celltrion a data package consisting of topline safety information, pharmacokinetic results and device performance, and the raw data (e.g., excel, SAS file, etc.) related to topline results, from such Phase 1 Trial (the "*Phase 1 Data*"). Celltrion will have thirty (30) days from delivery of the Phase 1 Data (the "*ROFN Exercise Period*") to exercise its ROFN by giving Rani written notice thereof (a "*ROFN Exercise Notice*"), which will specify the country(ies) with respect to which the ROFN is being exercised (the "*ROFN Territory*"). Prior to and during the ROFN Exercise Period and, if the ROFN is validly exercised, during the ROFN Negotiation Period, Rani will not negotiate with Third Parties with respect to a license to commercialize Product and will not provide to Third Parties confidential information about Product for such purpose.

5.2. Exercise of ROFN. During the ROFN Exercise Period, Rani will use best reasonable efforts to promptly provide to Celltrion any additional information regarding the Product, the Rani Oral Delivery Technology, and/or the Phase 1 Trial of the Product, which is reasonably requested by Celltrion and relevant to a decision whether to exercise the ROFN; provided that, Rani will not have any obligation to provide information not related or specific to Product development and commercialization, or to perform any additional studies or analysis in order to generate such information.

5.3. Negotiation Period. If Celltrion delivers to Rani a ROFN Exercise Notice within the ROFN Exercise Period, then Celltrion will have an exclusive period of ninety (90) days from delivery of the ROFN Exercise Notice (the "*ROFN Negotiation Period*") to negotiate in good faith a definitive agreement with Rani for rights to clinically develop and commercialize Product in the ROFN Territory. Such definitive agreement would include (but not necessarily limited to) (a) supply terms for Rani to exclusively supply Product (in finished form) for Celltrion to conduct clinical development and commercialization of Product in the ROFN Territory (including without limitation forecast and order procedures, shipment and delivery, stability testing, lot size and provisions for continuity of future supply), (b) establishment of a joint committee to oversee development plans for the ROFN Territory, to ensure consistency and coordination of clinical trials across the Rani Territory and the ROFN Territory, and (c) grant of rights and license by Rani to Celltrion (and/or its Affiliate) to clinically develop and commercialize Product for exclusive commercialization in the ROFN Territory. Rani will have the right to continue to advance development of Product during the ROFN Exercise Period and ROFN Negotiation Period. Rani will have no obligation to enter into a definitive agreement without a Commercial Supply Agreement being agreed at the same time.

5.4. Definitive Agreement. If the Parties enter into a definitive agreement for the clinical development and exclusive commercialization of Product in the ROFN Territory following exercise of the ROFN, such agreement will set forth the respective roles and responsibilities of the Parties for such arrangement. Rani would continue to have final decision-making authority over development and commercialization of Product in the Rani Territory; however, global development plans for Product (including studies that impact countries in both the Rani Territory and ROFN Territory) would be discussed and decided through a joint committee. It is also expected that Celltrion would be solely responsible to conduct, and bear the costs of, all clinical development and commercialization of Product for the ROFN Territory, including seeking and obtaining regulatory approvals, and Rani would provide cooperation reasonably requested therefor, including responding to Governmental Authorities regarding matters related to or involving Rani's Oral Delivery Technology or the manufacture, development or commercialization of Product outside the ROFN Territory. It is expected that any definitive agreement for the clinical development and commercialization of Product in the ROFN Territory would include an upfront payment, milestones and royalties to Rani in exchange for such rights.

5.5. End of ROFN. In the event Celltrion does not deliver a ROFN Exercise Notice within the ROFN Exercise Period, 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 in the ROFN Territory within the ROFN Negotiation Period, then the ROFN will terminate and Rani will have no further obligations under this Agreement related to a ROFN or the negotiation of rights related to Product. Neither the exercise nor the termination of the ROFN will affect the Parties' other rights and obligations under this Agreement or any other then-existing definitive agreement(s), including without limitation any existing obligations with respect to the supply of DP and/or DS by Celltrion.

6. MANUFACTURE AND SUPPLY

6.1. Supply. Rani will obtain supply of Drug Product and/or Drug Substance exclusively from Celltrion (or its Affiliate) for the clinical development and commercialization of Product, subject to the other provisions of this Agreement including without limitation Section 6.9 (Supply Continuity). Rani will use Drug Product and/or Drug Substance solely for the manufacture, development and commercialization of Product, as permitted under this Agreement. For clarity, unless otherwise agreed by the Parties, Stage 1 Supply, Stage 2 Supply and Stage 3 Supply will be in the form of Drug Substance.

6.2. Initial Supply. Unless agreed otherwise by the Parties, Rani will order an initial quantity of Stage 1 Supply ("*Initial Supply*") [*] by placing an Order therefor with Celltrion [*], and for clinical supply of Drug Substance beyond the Initial Supply in accordance with Section 6.3.2 below (Orders). If needed, Rani may order additional quantities of Stage 1 Supply by placing Orders therefor with Celltrion as set forth in Section 6.3.2 below (Orders).

6.3. Additional Clinical Supply.

6.3.1. *Forecasts*. Unless otherwise mutually agreed by the Parties, Rani will provide to Celltrion on or before [*] of each calendar year a written, nonbinding forecast of its clinical requirements for Drug Product and/or Drug Substance for the subsequent calendar year. During each calendar year, Rani will promptly notify Celltrion in the event there is a material change to Rani's forecast of clinical requirements for Drug Product and/or Drug Substance. Upon receipt of each forecast or changed forecast, Celltrion will promptly notify Rani in the event Celltrion foresees any difficulty supplying Rani the forecasted amount of DP and/or DS for the applicable calendar year.

6.3.2. *Orders*. For clinical supply of Drug Product and/or Drug Substance beyond the Initial Supply, Rani will place orders for Drug Product and/or Drug Substance with Celltrion by providing binding written purchase orders of its requirements of Drug Product and/or Drug Substance at least [*] days in advance ("*Orders*"), unless otherwise mutually agreed by the Parties. Each Order will specify the quantity of Drug Product and/or Drug Substance and the proposed delivery date. The minimum order quantity for Drug Substance shall be as set forth in Appendix A (Supply Price Schedule). Celltrion will use commercially reasonable efforts to supply Drug Product and/or Drug Substance to Rani in accordance with each Order. If Celltrion reasonably believes that it will not be able to meet an Order as provided, it will promptly notify Rani in writing within [*] days of receiving such Order. In such event, the Parties will discuss in good faith how best to meet Rani's requirements of Drug Product and/or Drug Substance set forth in the Order.

6.4. Manufacturing and Delivery.

6.4.1. *Specifications*. Drug Product and/or Drug Substance supplied by Celltrion hereunder will be manufactured in accordance with cGMP, the Quality Agreement, the Specifications and applicable Law. Celltrion will be responsible for keeping its manufacturing facility and manufacturing processes for Drug Product and/or Drug Substance in compliance with cGMP, and applicable Law and regulatory requirements. Unless otherwise mutually agreed, Celltrion will deliver Drug Product and/or Drug Substance in the form set forth in Appendix A (Supply Price Schedule) in containers that are in accordance with Celltrion's specifications.

6.4.2. *Delivery*. Celltrion will deliver Drug Product and/or Drug Substance to Rani FCA (Celltrion Plant) (Incoterms 2020). Notwithstanding such Incoterms, Celltrion will be responsible for handling customs clearance with respect to DP and/or DS. Celltrion will be responsible for the manufacturer's release of Drug Product and/or Drug Substance. Celltrion will provide to Rani upon release of each lot of Drug Product and/or Drug Substance complete and accurate certificates of analysis, certificates of compliance, executed batch records, and deviations and related documentation (the "*Disposition Package*"). As Rani may request from time to time, Celltrion will make analytical methods used for testing and release of Drug Product and/or Drug Substance and test results, and such other documentation reasonably requested, available for Rani's inspection, which records will be complete and accurate.

6.4.3. *Minimum Shelf Life*. Upon delivery hereunder, Drug Product and/or Drug Substance supplied by Celltrion will have a minimum residual shelf life of not less than [*] of its approved shelf life (and, in any event, no less than [*] months of minimum residual shelf life), prior to any re-testing that may be available to extend the retest date. Upon reasonable request by Rani and mutual agreement by Celltrion, which will not be unreasonably withheld, Celltrion will perform retesting of DP and/or DS and provide retest results and an updated certificate of analysis to Rani.

6.4.4. *Non-Conforming DP/DS*. In the event that any DP and/or DS released by Celltrion and delivered hereunder fails to conform with the Specifications at the time such DP and/or DS is delivered to Rani, Rani may reject the same by giving written notice thereof to Celltrion (a "*Notice*"), within [*] days after receipt of the DP and/or DS at Rani's facility, and for latent defects, within [*] days after discovery of such latent defect, which Notice will specify the manner in which the DP and/or DS fails to conform to the Specifications. If Rani reasonably suspects that any DP and/or DS hereunder fails to conform to the Specifications, Rani may provide Notice to Celltrion, during the time periods described above, and the period for Rani to accept or reject such DP and/or DS will be extended by the period reasonably required to complete an inspection of such DP and/or DS and subsequent investigation, if any; provided that, Rani will target conclusion of any such inspection and investigation within [*] days of commencement of such inspection. If Celltrion disagrees with Rani's conclusion with respect to the non-conformance of such DP and/or DS, Celltrion will have the right to request that Rani submit its investigation report to an independent Third-Party expert mutually agreed upon by the Parties for review. Such independent Third-Party expert will review and make a determination as to non-conformance, and such expert's report will be shared with both Parties and its conclusion will determine conformance or non-conformance with the Specifications. The cost of such expert review will be borne by the Party whose position was contrary to the expert's determination (i.e., Rani if the expert determines the DP and/or DS conformed to Specifications at the time of delivery, or Celltrion if the expert determines the DP and/or DS did not so conform at the time of delivery).

6.4.5. *Changes to Manufacturing*. If changes to the Specifications of DP and/or DS are required, Celltrion will provide prior notification to Rani. Following the change of control process, where required, necessary regulatory applications may be submitted to regulatory authorities. All other updates, including regulatory authorities' approval, will be implemented in accordance with change of control process, and be notified to Rani. Any reasonable and documented additional costs incurred by Rani as a result of any changes to the Specifications of the DP and/or DS shall be borne by Celltrion. Celltrion will notify Rani in writing of any changes in or to the Specifications, Celltrion's manufacturing facilities or procedures, vendors, raw materials or capital equipment that will or may require Rani to amend its Regulatory Filings related to Product or otherwise as reasonably necessary to enable Rani to fulfill its regulatory obligations with respect to Product.

6.5. Commercial Supply. Promptly following the Order Date for the Initial Supply, Celltrion will use its reasonable efforts to facilitate discussions among Celltrion, Rani and [*] with respect to a commercial supply agreement for Stage 3 Supply of Drug Substance ("*Commercial Supply Agreement*") and a corresponding quality agreement. Celltrion and Rani will cooperate in good faith with an aim toward working out with [*] basic commercial supply terms within [*] after the Effective Date. It is acknowledged and understood that Rani may choose to stop or pause its preclinical and/or clinical activities with respect to Product at any time if it believes the parties are not making sufficient progress toward agreeing upon commercial supply terms and/or executing a commercial supply agreement.

6.6. Quality Agreement. Within thirty (30) days after the Effective Date, the Parties will enter into a quality agreement governing the quality and specifications of clinical Drug Product and/or Drug Substance to be supplied hereunder. Such quality agreement will be documented in writing, and will be regularly updated as needed by mutual written agreement of the Parties.

6.7. Rani Inspections. Subject to the terms and conditions of this Agreement, Rani may visit and inspect, no more than [*], at its own expense, Celltrion's (a) manufacturing facilities for Drug Product and/or Drug Substance, (b) quality control and analytical laboratories for the testing of Drug Product and/or Drug Substance, and (c) documents and records relating to (a) and (b) above or as otherwise reasonably requested, in each case to the extent such facilities or records relate to the Drug Product and/or Drug Substance supplied to Rani pursuant to this Agreement ("*Routine In-Person Audit*"). For Routine In-Person Audits, [*]. In case of a significant quality issue that affects the Drug Product and/or Drug Substance, the Parties may discuss to allow a for cause audit. Rani's inspections will be limited in scope to what is reasonably necessary to confirm that Celltrion complies, or has complied, with cGMP, this Agreement and the Quality Agreement in manufacturing the Drug Product and/or Drug Substance. Rani will coordinate all inspections with Celltrion and provide Celltrion with no less than [*] days prior written notice of any proposed routine inspection, and each in-person inspection will be [*] unless otherwise agreed between the Parties. The Parties will agree on timing and scope for any for cause audits, based on the exigency of the matter at issue. In addition, Celltrion will reasonably consider any specific requests from Rani for quality-related documentation outside of an in-person inspection. Inspections will be conducted in accordance with Celltrion's reasonable procedures during normal hours of operation. Any information obtained by Rani in the course of such inspections will be treated as Celltrion Confidential Information. [*]

6.8. Shortage Allocation. In the event of a shortage of Drug Product and/or Drug Substance such that Celltrion reasonably believes that it will not be able to supply Rani's requirements, Celltrion will promptly provide written notice to Rani thereof. If Celltrion actually cannot supply (a) Rani's Orders in full in accordance with the Agreement and (b) Celltrion's requirements for Drug Product and/or Drug Substance (including its obligations to licensees or distributors of Celltrion), then Celltrion will reasonably allocate Drug Product and/or Drug Substance such that each of Rani and Celltrion (together with its licensees or distributors) will suffer a pro rata shortage, determined by reference to the Drug Product and/or Drug Substance requirements of Rani as forecast by Rani and the requirements of Celltrion (together with its licensees and distributors) forecast by Celltrion.

6.9. Supply Continuity. In case Celltrion is unable to, or reasonably believes that it will not be able to, supply Rani's requirements of Drug Product and/or Drug Substance under this Agreement, Celltrion will promptly notify Rani of any actual or potential disruption to its ability to supply Drug Product and/or Drug Substance to Rani in full in accordance with the terms of this Agreement (a "*Supply Disruption*"). In such event, the Parties will promptly meet to discuss such situation and to seek a mutually agreeable mitigation or resolution to the Supply Disruption (which could include, without limitation, build-up of inventory, or other solutions). During any Supply Disruption, Rani, subject to [*] days' prior written notice to Celltrion, will have the right to obtain supply of Drug Product and/or Drug Substance or other adalimumab biosimilar for use in Product from Third Parties ("*Alternate Supply*") as it determines to be reasonably necessary or appropriate to avoid or remedy a Supply Disruption (including, without limitation, such period(s) or quantities of supply to which Rani has to reasonably commit in order to obtain supply from such Third Parties with respect to a Supply Disruption). If, as of the time Celltrion has remedied a Supply Disruption (and no further Supply Disruption is foreseeable), Rani will use reasonable efforts to transition back to use of Celltrion supply of DP and/or DS hereunder if and when reasonably practicable, provided that it would not unduly interfere with Rani's continued development, manufacture or commercialization of Product as determined by Rani in its reasonable judgment. Celltrion will reimburse Rani for the difference between the costs of obtaining Alternate Supply and the cost of obtaining such supply from Celltrion, as well as costs associated with mitigation activities with respect to a Supply Disruption hereunder (and Rani may offset such costs against any amounts owed to Celltrion hereunder), in addition to any other remedies available at law or in equity.

7. PAYMENT

7.1. Supply Price. Rani will pay Celltrion for the supply of Drug Product and/or Drug Substance as set forth in the Supply Price Schedule attached to this Agreement as Appendix A.

7.2. Reimbursement. Any reimbursement for FTE time expressly contemplated under this Agreement will be billed on an hourly basis, multiplying the number of reimbursable hours worked times the FTE Rate. Any reimbursement of out-of-pocket costs expressly contemplated under this Agreement will be billed at cost, with no mark-up. The Party to be reimbursed will include appropriate documentation for reimbursable costs, in such detail reasonably agreed by the Parties, with any invoice submitted therefor.

7.3. Invoices. Upon delivery of supply of Drug Product and/or Drug Substance in accordance with the terms of this Agreement, Celltrion will invoice Rani the applicable supply price for Drug Product and/or Drug Substance delivered. For any other amounts that are payable or reimbursable hereunder, the applicable Party will invoice the other Party for the amount of such payment or reimbursement. The invoicing Party will itemize in the invoice, and include with the invoice, copies of appropriate documentation for any reimbursable costs incurred. All undisputed invoices will be payable within [*] days of receipt. All invoices will be in U.S. Dollars. Each Party will provide the other Party promptly upon request with any reasonably requested information related to withholding taxes or otherwise reasonably required to process payment.

7.4. Payment Method. All payments made hereunder between the Parties will be made in U.S. Dollars. Each Party will pay all sums due hereunder by check, wire transfer, or electronic funds transfer (EFT) in immediately available funds. Each Party will promptly notify the other Party of the appropriate account information to facilitate any such payments. All amounts payable under this Agreement will be paid in full (subject to Section 7.8 (Withholding)).

7.5. Currency Conversion. With respect to each calendar quarter, for countries other than the United States, whenever conversion of payments from any foreign currency is required, such conversion will be made at the average rate of exchange for the currency of the applicable country during the calendar quarter to which such payments relate, as reported in *Bloomberg Professional*, a service of Bloomberg L.P., or in the event *Bloomberg Professional* is not available then *The Wall Street Journal*.

7.6. Audits. Each Party will keep complete and accurate records pertaining to its activities hereunder for which the other Party is obligated to pay or reimburse such Party, in sufficient detail to permit the paying Party to reasonably confirm the accuracy of all payments due hereunder and such records will be open (in such form as may be available or reasonably requested by a certified public accountant in accordance with this Section 7.6 (Audits)) to inspection for [*] following the end of the period to which they pertain. Each Party will have the right, at its own expense, to have an independent, certified public accountant, selected by it review such records of the other Party upon reasonable notice and during regular business hours and under reasonable obligations of confidentiality. The report of such accountant will be made available to both Parties simultaneously, promptly upon its completion; *provided, however*, that the Party being audited will have the right to review and comment on the final draft version of the report prior to it being finalized. Each Party's audit rights with respect to any calendar year shall expire [*] after the end of such year and the books and records for any particular calendar year will only be subject to [*] audit. If the inspection leads to the discovery of a discrepancy to the auditing Party's detriment, then the other Party will pay to the auditing Party the amount of the discrepancy. If the inspection leads to the discovery of a discrepancy to the detriment of the Party being audited, then the auditing Party will pay to the Party being audited the amount of the discrepancy. The auditing Party will pay the full cost of the inspection unless the discrepancy is to the detriment of the auditing Party and is greater than [*] of the amount actually paid for the audited period, in which case the Party being audited will pay the cost of such inspection.

7.7. Taxes. All Taxes levied on account of a payment made by one Party to the other Party pursuant to this Agreement may be subject to the withholding and remittance provisions of Section 7.8 (Withholding).

7.8. Withholding. In the event that Law requires one Party to pay or withhold Taxes with respect to any payment to be made by the Party pursuant to this Agreement, the Party will notify the other Party in writing of such payment or withholding requirements prior to making the payment to the other Party and provide such assistance to the other Party, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary in the other Party's efforts to claim an exemption from or reduction of such Taxes. The paying Party will, in accordance with Law, withhold Taxes from the amount due, remit such Taxes to the appropriate tax authority, and furnish the other Party with proof of payment of such Taxes

promptly following obtaining the relevant payment certificate. If Taxes are paid to a tax authority, the paying Party will provide such assistance to the other Party as is reasonably required to obtain a refund of Taxes withheld, or obtain a credit with respect to Taxes paid.

7.9. Late Payment. Any payments or portions thereof due hereunder which are not paid when due will bear interest at the Contract Interest Rate calculated on the number of days such payment is delinquent. This Section 7.9 (Late Payment) will in no way limit any other remedies available to either Party.

7.10. Appropriate Compensation. In addition to the ROFN and other non-financial consideration granted by Rani to Celltrion under this Agreement, the Parties agree that the payments for supply of Drug Product and/or Drug Substance represent the mechanism and overall monetary value agreed by the Parties for compensating Celltrion for the rights and license granted hereunder and the supply of Drug Product and/or Drug Substance.

7.11. Sublicense Payments. Celltrion will be responsible for any Third-Party license payments, milestones and royalties owed with respect to the manufacture, use, supply, or sale of Drug Product and/or Drug Substance under this Agreement in connection with Product, with respect to intellectual property that: (a) is licensed by Celltrion prior to or as of the Effective Date or (b) is licensed or acquired by Celltrion after the Effective Date without Rani's prior written agreement.

7.12. No Additions or Deductions. Except as expressly set forth in this Agreement, neither Party will have the right to add any additional charges to, or make any deductions from, amounts otherwise payable pursuant to this Agreement on account of any royalty or other amount payable by such Party to any Third Party.

8. INTELLECTUAL PROPERTY

8.1. Program Inventions.

8.1.1. *Ownership*. Celltrion will own Program Inventions solely related and limited to the Drug (but no other composition or subject matter including adalimumab or biosimilars thereto or other TNF-α molecules, other than Drug), including without limitation the composition, formulation (except as noted below), manufacture or use of Drug. Rani will own all other Program Inventions, including Program Inventions that relate to the formulation of molecules for use in Rani Oral Delivery Technology, including without limitation microtablet formulations of Drug, and oral dosing regimens.

8.1.2. *License*. Rani grants to Celltrion a perpetual, exclusive, royalty-free, worldwide right and license, with the right to sublicense, under Program Inventions solely to [*].

8.2. Cooperation. Each Party will promptly notify the other upon becoming aware (a) of any suspected or threatened material infringement of any Licensed IP, or (b) of any claim that Rani's, or its Affiliates' or sublicensees', exercise of the rights granted under the Licensed IP hereunder infringes any rights or Patents of a Third Party.

8.3. Patent and IP Handling. Each Party, at its sole cost, will have the sole right, but not the obligation, to (a) handle preparation, filing, prosecution, maintenance and defense (including responses to patent office communications, any office actions, oppositions, interferences and challenges (whether before a patent authority or judicial body) of its Patent rights and other intellectual property rights, (b) enforce its patent rights and other intellectual property rights against any actual, alleged or threatened infringement or misappropriation by Third Parties (including without limitation the handling of oppositions, and (c) settle any such matters in its sole discretion, subject to its obligations, and the licenses and rights granted, under this Agreement.

8.4. Defense and Settlement of Third-Party Claims. If a Third Party asserts against a Party (or its Affiliates) that a Patent right or other right owned by the Third Party is infringed by the manufacture, use, sale, offer for sale, importation or exploitation of Product in the course of a Party or its Affiliate performing its rights and obligations under this Agreement, such Party will promptly notify the other Party and will have the sole right to defend itself against such claims. Upon request of the named Party, the other Party will reasonably

cooperate with the named Party with respect to the defense of such claims, and the named Party will reimburse the other Party any reasonable, documented, out-of-pocket costs incurred in connection therewith.

8.5. Program Data. Rani will own all data and know-how generated in the performance of the Agreement ("*Program Data*"). Rani will provide to Celltrion, and grants to Celltrion a right to use, Program Data applicable to Drug as set forth in Section 4.4 (Safety Matters).

9. CONFIDENTIALITY AND PUBLICATIONS

9.1. Confidentiality. Confidentiality obligations of the Parties under this Agreement with respect to Confidential Information shall be governed by the Mutual Confidentiality and Non-Disclosure Agreement between the Parties dated May 26, 2023 (the "*Confidentiality Agreement*"). All Confidential Information exchanged between the Parties under this Agreement will be deemed Confidential Information of the Disclosing Party and will be subject to the terms of the Confidentiality Agreement.

9.2. [Not used]

9.3. Terms and Conditions Confidential. Neither Party will disclose the terms and conditions of this Agreement except as may be required by Law. Notwithstanding the foregoing, if a Party is required by Law or the rules of any securities exchange or automated quotation system to make any such disclosure of this Agreement, it will, except where impracticable for necessary disclosures, give reasonable advance notice to the other Party of such disclosure requirement and the Parties will consult with one another concerning which terms of this Agreement will be requested to be redacted in any public disclosure of the Agreement, and in any event each Party will seek reasonable confidential treatment for any public disclosure by any such Governmental Authority. Each Party will have the right to disclose this Agreement to potential acquirors, investors or lenders of such Party, as a part of their due diligence investigations, provided that such potential acquirors, investors or lenders have agreed in writing to keep the terms of this Agreement confidential and to use such confidential information solely for the purpose permitted pursuant to this Section 9.3 (Terms and Conditions Confidential). Each Party will have the right to issue press releases in regards to this Agreement with the prior written agreement of the other Party or as required to comply with any Law or by the rules of any stock exchange or automated quotation system (in the case of such required disclosure, by providing reasonable advance notice to the other Party and reasonably considering comments provided by such other Party). Notwithstanding the foregoing, the Parties will agree upon an initial press release to announce the execution of this Agreement; thereafter, each Party may disclose to Third Parties the information contained in such press release without the need for further approval by the other Party.

9.4. [Not used].

9.5. Data; Publications and Presentations. Rani will own all data related to the research, development, manufacture, regulatory activities and commercialization of Product conducted by Rani hereunder ("*Rani Data*"). Rani will have the right to publish and present publicly (e.g., at meetings of healthcare professionals, conferences, symposia) Rani Data, provided however, that Rani will not disclose any Confidential Information of Celltrion, including Celltrion Confidential Information related to Drug, without Celltrion's prior written approval, which it shall not unreasonably withhold. If Celltrion reasonably requests to publish and present publicly (e.g., at meetings of healthcare professionals, conferences, symposia) Rani Data, Rani will consider such request in good faith (it being understood that Rani will have priority in publishing data related to Product, and that it is reasonable for Rani to withhold consent in order to preserve an opportunity to seek protection for intellectual property, to protect business-sensitive information, or to preserve Rani's publication strategy). Rani will have a right to review in advance and prior to granting its consent, any publication of Rani Data proposed by Celltrion, and may require removal of Rani Confidential Information from any such publication.

9.6. Attorney-Client Privilege. Neither Party is waiving, nor shall be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including

Confidential Information related to pending or threatened litigation) to the receiving Party, regardless of whether the disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections.

9.7. National Core Technology. Celltrion owns certain technology relating to large scale animal-cell culture and purification of antibodies of over 10,000 liters, and certain information regarding such is Celltrion National Core Technology. Celltrion National Core Technology is protected by the laws of the Republic of Korea (specifically, the ACT ON PREVENTION OF DIVULGENCE AND PROTECTION OF INDUSTRIAL TECHNOLOGY) and requires Celltrion (a) to take sufficient measures to prevent divulgence of Celltrion National Core Technology; and (b) to obtain approval from the applicable Korean governmental agency to export the Celltrion National Core Technology to a foreign enterprise; and (c) to list all the Rani personnel who has or shall have access to Celltrion National Core Technology. Rani agrees and acknowledges that (i) Celltrion has a right to perform due diligence on Rani to determine whether Rani's information protection measures meet Celltrion's relevant policy for the same; and (ii) any exportation of Celltrion National Core Technology to Rani (if applicable) shall only occur after such potential exportation has been reviewed and approved by the applicable Korean governmental agency. Celltrion shall use its reasonable best efforts to obtain prompt review and approval of any such potential exportation. Confidentiality obligations related to Celltrion National Core Technology shall be covered by and addressed in and through the Confidentiality Agreement.

10. Representations, Warranties and Covenants

10.1. Mutual Representations and Warranties. Each of the Parties hereby represents and warrants as of the Effective Date as follows:

10.1.1. It is duly organized and validly existing under the Laws of its jurisdiction of organization and it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement;

10.1.2. This Agreement is a legal and valid obligation binding upon such Party and enforceable in accordance with its terms; the execution, delivery and performance of the Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, by which it is bound, nor violate any Law;

10.1.3. To its knowledge, no government authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Authority, under Law, is or will be necessary for, or in connection with, the entering into of this Agreement or the transaction contemplated by this Agreement, or (except for regulatory approvals, licenses, clearances and the like necessary for the research, development, manufacture, sales or marketing of pharmaceutical products and except for any required filing with the U.S. Securities and Exchange Commission) for the performance by it of its obligations under this Agreement; and

10.1.4. It has not granted any right to any Third Party relating to its respective intellectual property, Drug Product, Drug Substance or Product which conflicts with the rights granted to the other Party hereunder.

10.2. Celltrion Representations and Warranties. Celltrion hereby represents that, as of the Effective Date:

10.2.1. Celltrion owns or otherwise Controls all of the rights, title and interest in and to the Licensed IP and Licensed Information and has the right to grant to Rani the rights therein purported to be granted to Rani under this Agreement;

10.2.2. Celltrion has developed the cell line and manufacturing process for Drug Product and Drug Substance in compliance with all applicable Laws and owns or Controls the right to use such cell line and manufacturing process for Drug Product and Drug Substance and to supply and sell such Drug Product and Drug Substance to Rani as contemplated by this Agreement;

10.2.3. In developing the cell line and manufacturing process for Drug Product and Drug Substance and in generating the Licensed Information, Celltrion has not used any employee or permitted subcontractor who is or has been debarred by any regulatory authority or is or has been the subject of debarment proceedings by any regulatory authority, or any person whose name appears on, or is associated with any name or entity on, the U.S. government's U.S. Department of Commerce Entity List and Denied Persons List, the U.S. Department of Treasury Specially Designated National and Blocked Persons List or the U.S. Department of State Debarred Parties List (these lists are available at http://www.bis.doc.gov/complianceandenforcement/listocheck.htm;

10.2.4. Celltrion warrants that Drug Product and Drug Substance supplied to Rani hereunder will be manufactured in accordance with applicable U.S. Laws (including cGMP) and the Quality Agreement and will, upon delivery, conform to the applicable Specifications for Drug Product or Drug Substance, as applicable, in effect at the time the Drug Product or Drug Substance is delivered to Rani hereunder;

10.2.5. Celltrion has not received any communication from any Third Party asserting or alleging that the development, manufacture, use or sale of Drug Product, Drug Substance or Drug misappropriates or infringes the rights of such Third Party (or if it has received such communication, it has settled or resolved such matter in a manner that preserves its rights to develop, manufacture, use or sell Drug Product, Drug Substance and Drug); and

10.2.6. Celltrion has not received any communication that a Governmental Authority has initiated, or intends to initiate, any investigation or action to withdraw any Regulatory Filing or Regulatory Approval with respect to the development, manufacture or commercialization of Drug Product, Drug Substance or Drug.

10.3. Rani Representations and Warranties. Rani hereby represents that, as of the Effective Date:

10.3.1. Rani owns or otherwise Controls all of the rights, title and interest in and to the Rani Oral Delivery Technology and has the right to grant to Celltrion the rights therein purported to be granted to Celltrion under this Agreement;

10.3.2. In developing Rani Oral Delivery Technology, Rani has not used any employee or permitted subcontractor who is or has been debarred by any regulatory authority or is or has been the subject of debarment proceedings by any regulatory authority, or any person whose name appears on, or is associated with any name or entity on, the U.S. government's U.S. Department of Commerce Entity List and Denied Persons List, the U.S. Department of Treasury Specially Designated National and Blocked Persons List or the U.S. Department of State Debarred Parties List (these lists are available at http://www.bis.doc.gov/complianceandenforcement/listocheck.htm; and

10.3.3. Rani has not received any communication from any Third Party asserting or alleging that the development, manufacture, use or sale of Product misappropriates or infringes the rights of such Third Party.

10.4. Disclaimer of Warranties. EXCEPT AS SET FORTH IN THIS ARTICLE 10 (REPRESENTATIONS, WARRANTIES AND COVENANTS), RANI AND CELLTRION EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THIS AGREEMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR NONINFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.

10.5. Mutual Covenants. Each of the Parties hereby covenants to the other Party as follows:

10.5.1. It will carry out its activities hereunder in compliance with Law; and

10.5.2. It will not grant to any Third Party any right that conflicts with the rights granted to the other Party hereunder.

10.6. Celltrion Covenants. Celltrion hereby covenants to Rani as follows:

10.6.1. Celltrion has and will maintain all necessary government permits, including without limitation, health and safety and environmental permits necessary for the conduct of the actions it undertakes pursuant to its manufacturing and supply obligations hereunder;

10.6.2. All data and information relating to Drug Product and/or Drug Substance to which Celltrion grants Rani a letter of authorization or right of reference, and Licensed Information provided by Celltrion to Rani hereunder, will be accurate and complete in all material respects when granted or provided;

10.6.3. Celltrion will keep in effect and maintain all Regulatory Filings and Regulatory Approvals to which it grants Rani a letter of authorization or right of reference hereunder;

10.6.4. Celltrion will not use in the performance of this Agreement any employee or permitted subcontractor who is or has been debarred by any regulatory authority or is or has been the subject of debarment proceedings by any regulatory authority, or any person whose name appears on, or is associated with any name or entity on, the U.S. government's U.S. Department of Commerce Entity List and Denied Persons List, the U.S. Department of Treasury Specially Designated National and Blocked Persons List or the U.S. Department of State Debarred Parties List (these lists are available at http://www.bis.doc.gov/complianceandenforcement/listocheck.htm); and

10.6.5. Celltrion (and, if applicable, its owners, officers, directors, employees and agents) have not and will not pay, give, offer or promise to pay or give, or authorize the payment, directly or indirectly, of any money or anything of value to any government official or employee (including employees of state-owned institutions), for the purpose of (a) influencing any act or decision of such official or of such government, (b) inducing that person to do or omit doing any act in violation of his or her lawful duty, (c) securing an improper advantage, or (d) influencing such official to use his influence with the government to effect or influence the decision of such government, in order to assist Celltrion and/or Rani in obtaining or retaining business for or with or directing business to any person.

10.7. Rani Covenants. Rani hereby covenants to Celltrion as follows:

10.7.1. Rani has and will maintain all necessary government permits, including without limitation, health and safety and environmental permits necessary for the conduct of the actions it undertakes pursuant to its rights obligations hereunder;

10.7.2. All data and information relating to Product provided by Rani to Celltrion hereunder will be accurate and complete in all material respects when provided;

10.7.3. Rani will not use in the performance of this Agreement any employee or permitted subcontractor who is or has been debarred by any regulatory authority or is or has been the subject of debarment proceedings by any regulatory authority, or any person whose name appears on, or is associated with any name or entity on, the U.S. government's U.S. Department of Commerce Entity List and Denied Persons List, the U.S. Department of Treasury Specially Designated National and Blocked Persons List or the U.S. Department of State Debarred Parties List (these lists are available at http://www.bis.doc.gov/complianceandenforcement/listocheck.htm); and

10.7.4. Rani (and, if applicable, its owners, officers, directors, employees and agents) has not and will not pay, give, offer or promise to pay or give, or authorize the payment, directly or indirectly, of any money or anything of value to any government official or employee (including employees of state-owned institutions), for the purpose of (a) influencing any act or decision of such official or of such government, (b) inducing that person to do or omit doing any act in violation of his or her lawful duty, (c) securing an improper advantage, or (d) influencing such official to use his influence with the government to effect or influence the decision of such government, in order to assist Celltrion and/or Rani in obtaining or retaining business for or with or directing business to any person.

11. Limitations of Liability; Insurance

11.1. Limitations of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, INCIDENTAL, EXEMPLARY OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE), EVEN IF SUCH PARTY WAS ADVISED OR OTHERWISE AWARE OF THE LIKELIHOOD OF SUCH DAMAGES. The limitations set forth in this Section 11.1 (Limitations of Liability) will not apply with respect to (a) either Party's indemnification obligations under Article 12 (Indemnification), (b) either Party's breach of the Confidentiality Agreement, or (c) gross negligence or willful misconduct of a Party.

11.2. Insurance. During the Term and for [*] years thereafter each Party will obtain and maintain insurance adequate to cover its obligations and activities hereunder with reputable and financially secure insurance carriers in a form and at levels as customary for a company of its size in the pharmaceutical industry (or reasonable self-insurance sufficient to provide materially the same level and type of protection).

12. Indemnification

12.1. Indemnity.

12.1.1. Subject to the remainder of this Article 12 (Indemnification) Rani will defend, indemnify, and hold harmless Celltrion, its Affiliates, and their respective directors, officers, employees and agents (solely to the extent acting within their agency) (collectively, *"Celltrion Indemnitees"*), at Rani's cost and expense, from and against any and all liabilities, losses, costs, damages, fees or expenses (collectively, *"Losses"*) (including reasonable legal expenses and attorneys' fees incurred by any Celltrion Indemnitees until such time as Rani has acknowledged and assumed its indemnification obligation hereunder with respect to the applicable Claim) arising out of any claim, action, lawsuit, or other proceeding (collectively, *"Claims"*) brought against any Celltrion Indemnitee by a Third Party to the extent such Losses result from (a) the negligence or willful misconduct of Rani, its Affiliates or agents in performing under this Agreement or the Confidentiality Agreement, (b) a breach by Rani of this Agreement or the Confidentiality Agreement, including any failure of Rani's representations or warranties in Section 10.1 (Mutual Representations and Warranties) and Section 10.3 (Rani Representations and Warranties) to be true, or (c) Rani's, its Affiliate's or its licensee's development, manufacture or commercialization of the Product, including product liability related to Product except to the extent related to Drug Product and/or Drug Substance manufacturing defects; but in each case above excluding such Losses to the extent they arise from (a), (b) or (c) of Section 12.1.2 below.

12.1.2. Subject to the remainder of this Article 12 (Indemnification), Celltrion will defend, indemnify, and hold harmless Rani, its Affiliates, and their respective directors, officers, employees and agents (solely to the extent acting within their agency) (collectively, *"Rani Indemnitees"*), at Celltrion's cost and expense, from and against any and all Losses (including reasonable legal expenses and attorneys' fees incurred by any Rani Indemnitees until such time as Celltrion has acknowledged and assumed its indemnification obligation hereunder with respect to the applicable Claim) arising out of any Claim brought against any Rani Indemnitee by a Third Party to the extent such Losses result from (a) the negligence or willful misconduct of Celltrion, or its Affiliates or agents in performing under this Agreement or the Confidentiality Agreement, (b) a breach by Celltrion of this Agreement or the Confidentiality Agreement, including any failure of Celltrion's representations or warranties in Section 10.1 (Mutual Representations and Warranties) and 10.2 (Celltrion Representations and Warranties) to be true, or (c) Celltrion's, its Affiliate's or its licensee's development, manufacture or commercialization of Drug or manufacturing defects with respect to Drug Product and/or Drug Substance; but in each case above excluding such Losses to the extent they arise from (a), (b) or (c) of Section 12.1.1 above.

12.2. Claim for Indemnification. A Rani Indemnitee or a Celltrion Indemnitee (the *"Indemnified Party"*) seeking indemnification under this Article 12 (Indemnification) will promptly notify the other Party (the *"Indemnifying Party"*) of the Claim or Loss and, when known, the facts constituting the basis for the Claim; *provided, however*, that the failure by an Indemnified Party to give such notice or to otherwise meet its obligations under this Section 12.2 (Claim for Indemnification) will not relieve the Indemnifying Party of its indemnification obligation under this Agreement except to the extent that the Indemnifying Party is actually prejudiced as a result of such failure. Except as set forth below in this Section, the Indemnifying Party will have exclusive control of the defense and settlement of all Claims for which it is responsible for indemnification and will promptly assume defense thereof at its own expense. The Indemnified Party may, at its own expense, participate in the defense of a Claim with counsel of its own choosing. The Indemnified Party will not settle or compromise such Claim for which it is entitled to indemnification without the prior written consent of the Indemnifying Party, unless the Indemnifying Party is in breach of its obligation to defend hereunder. In no event will the Indemnifying Party settle any Claim without the prior written consent of the other Party if such settlement does not include a complete release from liability on such Claim or if such settlement would involve undertaking an obligation other than the payment of money, would bind or impair the other Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of the other Party is invalid or unenforceable. The Indemnified Party will reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense.

13. TERM AND TERMINATION

13.1. Term. This Agreement will come into effect as of the Effective Date and remain in effect until terminated in accordance with this Article 13 (Term and Termination).

13.2. Termination. This Agreement may be terminated as follows:

13.2.1. *Mutual Agreement*. The Parties may terminate the Agreement at any time upon mutual agreement.

13.2.2. *Termination for Convenience.* Rani will have the right to terminate this Agreement at any time (a) prior to [*], upon [*] days' prior written notice to Celltrion, and (b) after [*], upon [*] days' prior written notice to Celltrion. Notwithstanding the foregoing in this Section 13.2.2 (Termination for Convenience), prior to completing a Phase 1 Trial with Product, Rani may [*]. Termination for convenience under this Section 13.2.2 shall not terminate automatically any definitive agreement entered into between the Parties following exercise of the ROFN (as set forth in Section 5 (Right of First Negotiation)) and/or the Commercial Supply Agreement.

13.2.3. *Phase 1 Delay.* Celltrion will have the right to terminate this Agreement if Rani fails to (a) Initiate a Phase 1 Trial with Product [*], or (b) deliver the Phase 1 Data to Celltrion [*], in each case commencing from delivery of the full amount of Initial Supply to Rani that complies with the terms of this Agreement. For clarity, if such Phase 1 Trial has multiple parts (e.g., a part 2 repeat-dose portion), then for purposes of the preceding sentence the Phase 1 Data shall mean solely the data related to the single-dose or single-ascending dose portion of such trial, as applicable. Such period will be extended for any delays caused by Celltrion, and if requested by Rani Celltrion will consider in good faith an extension if there are delays caused by matters outside the Parties' reasonable control. If Rani intends to extend such period for any delay it believes is caused by Celltrion, it will promptly notify Celltrion so the Parties can confirm or dispute such proposed extension.

13.2.4. *Termination for Material Breach.* If either Party believes that the other Party is in material breach of this Agreement, then such Party may deliver notice of such material breach (specifying the nature of the breach in reasonable detail) to the other Party. If the breaching Party (or its Affiliate) fails to cure such material breach within [*] days after the receipt of such notice (or [*] days with respect to any failure to pay amounts due hereunder), then the other Party will be permitted to terminate this Agreement by written notice; *provided, however*, if the breaching Party notifies the other Party within such [*] day period (or [*] day period with respect to failure to pay amounts due hereunder) that it disagrees in good faith with such asserted basis for termination, this Agreement will not

terminate unless and until the matter has been finally resolved in accordance with Section 14.3 (Governing Law; Arbitration).

13.2.5. *Termination for Safety Concerns*. If either Party has a serious concern about the safety of Drug Product, Drug Substance or Product, taking into consideration the balance of harm and benefit to patients, the Parties will seek to resolve such concern in good faith. If the Parties are not able to resolve the concern, either Party may raise the matter for discussion between senior executives of the Parties (or their designees), and the Parties will use reasonable efforts to cause their senior executives (or designees) to meet promptly to discuss such concern. If after such senior executives (or designees) meet, [*]

13.3. Effect of Termination. In the event of any termination of this Agreement: (a) any liabilities previously accrued will survive; (b) the rights and licenses granted by one Party to the other Party hereunder will terminate, unless expressly stated to survive in Section 13.4 (Surviving Provisions); (c) each Party will return to the other Party or destroy all Confidential Information of the other Party as set forth in the Confidentiality Agreement; and (d) in the case of a termination for convenience under Section 13.2.2, Rani will pay Celltrion for any supply of DP and/or DS or in-process supply of DP and/or DS as of such time, which was manufactured in response to a Rani Order delivered prior to such notice of termination. Rani shall have the right to use any remaining inventory of DP and/or DS in its possession as of the termination date, subject to and in accordance with the terms of this Agreement, which shall survive termination with respect to such use.

13.4. Surviving Provisions. In addition to any provisions herein that are expressly stated to survive termination, in the event of any termination of this Agreement the following provisions shall survive: Section 3.1(b) (License to Rani) and 3.2 (Licensed Information) solely with respect to Licensed Information incorporated, used or referenced in Rani Regulatory Filings, Regulatory Approvals, program materials or the program as of the date of termination, 8.1.2 (License), Article 9 (Confidentiality and Publications), Article 11 (Limitations of Liability; Insurance); Article 12 (Indemnification); Article 13 (Term and Termination) and Article 14 (Miscellaneous); provided, however, that the aforementioned Section 3.1(b) (License to Rani) and 3.2 (Licensed Information) provisions shall survive termination only in the instance where termination occurred due to termination for material breach (Section 13.2.4 (Termination for Material Breach)) of the Agreement due to material breach of Celltrion.

14. MISCELLANEOUS

14.1. Affiliates. Each Party will have the right to exercise its rights and perform its obligations hereunder through its Affiliates; provided that, such Party will be responsible for its Affiliates' performance hereunder.

14.2. Assignment. Neither Party may assign or otherwise transfer this Agreement without the prior written consent of the other Party; however, either Party may assign or transfer this Agreement to an Affiliate, or to a successor in connection with a merger, acquisition, or sale of substantially all its assets to which this Agreement relates. Any assignment not in accordance with this Agreement will be void ab initio. Subject to the foregoing, the rights and obligations of the Parties under this Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.

14.3. Governing Law; Arbitration. This Agreement shall be governed by, and enforced and construed in accordance with, the laws of the State of Delaware without regard to its conflicts of law provisions, except as to any issue which depends upon the validity, scope or enforceability of any Patent, which issue will be determined in accordance with the laws of the country in which such patent was issued. In the event of any controversy or dispute arising out of or relating to any provision of this Agreement, the construction, validity or breach thereof, the Parties will try in good faith to settle the same amicably between themselves. If they fail to reach a resolution amicably within thirty (30) days after giving notice of the dispute to the other Party, such controversy or dispute will be exclusively and finally settled by arbitration. Such arbitration will be held in [*] under the rules of the International Chamber of Commerce. The award of arbitration shall be final and binding upon both parties. The official language of the arbitration shall be English. The arbitration shall be decided by three (3) arbitrators. The arbitrators shall not have the power to grant any award or remedy

other than such awards or remedies that are available under the applicable law. Notwithstanding the foregoing, each Party understands and agrees that a Party will be entitled to seek injunctive and/or equitable relief and enforcement of any arbitration award from the applicable courts in any appropriate jurisdiction. The Parties agree that a final judgment in any such matter will be conclusive and may be enforced in other jurisdictions by suits on the judgment or in any other manner provided by law. Any proceeding brought by either Party under this Agreement will be exclusively conducted in the English language. The United Nations Convention for the International Sale of Goods will not apply to the transactions contemplated herein.

14.4. Construction. The Parties each acknowledge that they have had the advice of counsel with respect to this Agreement, that this Agreement has been jointly drafted, and that no rule of strict construction shall be applied in the interpretation hereof. Headings and captions are for convenience only and are not to be used in the interpretation of this Agreement. The words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation". The words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof. All references herein to Articles, Sections, Schedules or Exhibits, unless otherwise specifically provided, will be construed to refer to Articles, Sections, Schedules or Exhibits of this Agreement. This Agreement has been executed in English, and the English version of this Agreement shall control. Unless otherwise agreed by the Parties, all information shared under this Agreement will be disclosed in the English language.

14.5. Counterparts. This Agreement may be executed in counterparts with the same effect as if both Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument. This Agreement may be executed by electronic signatures (e.g., using DocuSign) or signatures transmitted by electronic means (e.g., facsimile, email, pdf format), each of which shall be deemed a valid and enforceable signature and means of delivery.

14.6. Entire Agreement. This Agreement, including any attached Appendices, Schedules and Exhibits, constitutes the entire agreement between the Parties as to the subject matter of this Agreement, and supersedes and merges all prior negotiations, representations, agreements and understandings regarding the same.

14.7. Force Majeure. Neither Party shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure is due to causes beyond its reasonable control, including acts of God, fires, floods, earthquakes, labor strikes, acts of war, terrorism or civil unrest (*"Force Majeure"*); *provided, however*, that the affected Party promptly notifies the other Party in writing (and continues to provide monthly status updates to the other Party for the duration of the effect); *and further provided* that the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and to mitigate the effect of such occurrence, and shall continue performance with reasonable dispatch whenever such causes are removed.

14.8. Further Assurances. Each Party agrees to do and perform all such further acts and things and shall execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.

14.9. No Set-Off. No Party shall have the right to deduct from amounts otherwise payable hereunder any amounts payable to such Party (or its Affiliates) from the other Party (or its Affiliates).

14.10. Notices. Any notice required or permitted to be given by this Agreement shall be in writing, in English, and shall be delivered by hand or overnight courier with tracking capabilities or mailed postage prepaid by registered or certified mail addressed as set forth below unless changed by notice so given:

If to Celltrion:

Celltrion, Inc.
19F, IBS Building, 263, Central-ro
Yeonsu-gu, Incheon 22006
Republic of Korea
Attention: Business alliance team leader
Telephone: [*]

If to Rani:

Rani Therapeutics, LLC
2051 Ringwood Ave.
San Jose, CA 95131
USA
Attention: General Counsel
Telephone: [*]

Any such notice shall be deemed given on the date delivered. A Party may add, delete (so long as at least one person is remaining), or change the person or address to which notices should be sent at any time upon written notice delivered to the other Party in accordance with this Section 14.10 (Notices).

14.11. Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute Rani and Celltrion as partners, agents or joint venturers. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

14.12. Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall negotiate in good faith to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

14.13. Third-Party Beneficiaries. Except as expressly provided with respect to Celltrion Indemnitees or Rani Indemnities in Article 12 (Indemnification), there are no third-party beneficiaries intended hereunder and no Third Party shall have any right or obligation hereunder.

14.14. Waivers and Modifications. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any breach of any provision hereof shall not be deemed to be a waiver of any other breach of such provision or any other provision on such occasion or any other occasion. No waiver, modification, release or amendment of any right or obligation under or provision of this Agreement shall be valid or effective unless in writing and signed by all Parties hereto.

****

(Signature page follows)

IN WITNESS WHEREOF, the Parties have executed this License and Supply Agreement as of the Effective Date.

RANI THERAPEUTICS, LLC	**CELLTRION, INC.**
By: /s/ Talat Imran	By: /s/ Woo Sung Kee
Name: Talat Imran	Name: Woo Sung Kee
Title: Chief Executive Officer	Title: Chief Executive Officer

Appendix A:
Supply Price Schedule

[*]

CONFIDENTIAL

Portions of this exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted material is of the type that the Registrant treats as private or confidential. Omitted portions are indicated by [*].

Appendix B:
FTE Rate Schedule

[*]

CONFIDENTIAL

Portions of this exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted material is of the type that the Registrant treats as private or confidential. Omitted portions are indicated by [*].

Portions of this exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted material is of the type that the Registrant treats as private or confidential. Omitted portions are indicated by [*].

RANI THERAPEUTICS, LLC.

Date

Kate McKinley
[*]

Re: Offer of Employment

Dear Kate,

RANI THERAPEUTICS, LLC. (the "Company") is pleased to offer you employment on the terms and conditions set forth in this letter agreement (the "Agreement").

1. EMPLOYMENT BY THE COMPANY.

(a)Position. Your employment with the Company as Chief Business Officer will start on May 22, 2023.

(b)Duties and Location. You will be responsible for duties and responsibilities as are customary for the position of Chief Business Officer and as may be directed by the Chief Executive Officer of the Company, to whom you will report. This position will be a remote role,a allowing you to work from your preferred location. As part of your role, the Company reserves the right to require you to visit our headquarters from time to time as well as require reasonable business travel. Subject to the terms of this Agreement, the Company may modify your job title, duties, and reporting relationship as it deems necessary and appropriate in light of the Company's needs and interests from time to time.

(c)Outside Activities. Throughout your employment with the Company, you may engage in civic and not-for-profit activities so long as such activities do not interfere with the performance of your duties hereunder or present a conflict of interest with the Company. During your employment by the Company, except on behalf of the Company, you will not directly or indirectly serve as an officer, director, stockholder, employee, partner, proprietor, investor, joint venturer, associate, representative or consultant of any other person, corporation, firm, partnership or other entity whatsoever known by you to compete with the Company (or is planning or preparing to compete with the Company), anywhere in the world, in any line of business engaged in (or planned to be engaged in) by the Company; provided, however, that you may purchase or otherwise acquire up to (but not more than) one percent (1%) of any class of securities of any enterprise (but without participating in the activities of such enterprise) if such securities are listed on any national or regional securities exchange.

2. COMPENSATION AND BENEFITS.

(a)Base Salary. Your base salary will be $390,000, per year and will be paid on the Company's ordinary payroll cycle, less applicable payroll deductions and withholdings. As an exempt salaried employee, you will be required to work the Company's normal business hours, and such additional time as appropriate for your work assignments and position, and you will not be entitled to overtime compensation.

(b)Employee Benefits. As a regular full-time employee, you will be eligible to participate in the Company's standard employee benefits offered to executive level employees, as in effect from time to time and subject to the terms and conditions of the benefit plans and applicable Company policies. A full description of these benefits is

available upon request. Subject to the terms of this Agreement, the Company may change your compensation and benefits from time to time in its discretion.

(c)Annual Bonus. You are also eligible to earn an annual bonus with a target amount equal to 75% of your annual base salary. The terms of this bonus will be determined in the sole discretion of the Board of Directors of Rani Therapeutics Holdings, Inc. (the "Board") or the Compensation Committee thereof.

(d)Equity Compensation. Subject to approval by the Board, the Company will grant you an option to purchase 250,000 shares of the Company's common stock (the "Option"). The Option shall vest over a four-year period, with one quarter (1/4) of the shares subject to the Option vesting on the one-year anniversary of the date of grant, and the remaining shares vesting equally over the following thirty-six (36) months of continuous service. The Option shall be issued pursuant to the terms and conditions of the Company's 2021 Equity Incentive Plan (the "Plan") and shall be governed in all respects by the terms of the Plan, the grant notices and the option agreements.

(e)Severance and Change in Control Benefit Plan. You will be eligible to participate in the Rani Therapeutics Holdings, Inc. Severance and Change in Control Plan (the "Severance Plan") subject to the terms and conditions of the Severance Plan and your Participation Agreement (as defined in the Severance Plan).

(f) Expenses. The Company will reimburse you for reasonable travel, entertainment or other expenses incurred by you in furtherance of or in connection with the performance of your duties hereunder, in accordance with the Company's expense reimbursement policies and practices as in effect from time to time.

3. Confidential Information. As a Company employee, you will be expected to continue to abide by Company rules and policies including those rules and policies regarding the protection of the Company's confidential information. You are also required to execute the Company's standard form of Confidentiality Agreement, to be provided to you.

4. At-Will Employment Relationship. Your employment relationship with the Company is at will. Accordingly, you may terminate your employment with the Company at any time and for any reason whatsoever simply by notifying the Company; and the Company may terminate your employment at any time, with or without cause or advance notice.

5. Compliance With or Exemption From Section 409A. It is intended that the benefits set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Internal Revenue Code of 1986, as amended, (the "Code") (Section 409A, together with any state law of similar effect, "Section 409A") provided under Treasury Regulations 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). With respect to reimbursements or in-kind benefits provided to you hereunder (or otherwise) that are not exempt from Section 409A, the following rules shall apply: (i) the amount of expenses eligible for reimbursement, or in-kind benefits provided, during any one of your taxable years shall not affect the expenses eligible for reimbursement, or in-kind benefit to be provided in any other taxable year, (ii) in the case of any reimbursements of eligible expenses, reimbursement shall be made on or before the last day of your taxable year following the taxable year in which the expense was incurred, (iii) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit.

6. Dispute Resolution.

(a)Arbitration Agreement. To ensure the rapid and economical resolution of disputes that may arise in connection with your employment with the Company, you and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, your employment with the Company, or the termination of your employment, shall be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. § 1-16, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS, Inc. or its successor

Portions of this exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted material is of the type that the Registrant treats as private or confidential. Omitted portions are indicated by [*].

("JAMS"), under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding**.

(b)Individual Claims. All claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law to be submitted to mandatory arbitration and such applicable law(s) are not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "Excluded Claims"). In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration.

(c)Process. You will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law.

(d)Injunctive Relief. Nothing in this letter agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

7. Miscellaneous. This Agreement, together with the other agreements referenced herein, forms the complete and exclusive statement of your employment agreement with the Company. It supersedes any other agreements or promises made to you by anyone, whether oral or written. Changes in your employment terms, other than those changes expressly reserved to the Company's or the Board's discretion in this Agreement, require a written modification approved by the Company and signed by a duly authorized officer of the Company (other than you). This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination shall not affect any other provision of this Agreement and the provision in question shall be modified so as to be rendered enforceable in a manner consistent with the intent of the parties insofar as possible under applicable law. This Agreement shall be construed and enforced in accordance with the laws of the State of California without regard to conflicts of law principles. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement, or rights hereunder, shall be in writing and shall not be deemed to be a waiver of any successive breach or rights hereunder. This Agreement may be delivered and executed via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic

Transactions Act or other applicable law) or other transmission method and shall be deemed to have been duly and validly delivered and executed and be valid and effective for all purposes.

SIGNATURE PAGE FOLLOWS

Portions of this exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted material is of the type that the Registrant treats as private or confidential. Omitted portions are indicated by [*].

Please sign and date this Agreement and return a signed copy to me on or before May 20, 2023 to confirm your acceptance of this Agreement.

RANI THERAPEUTICS, LLC

/s/ Bella Vazquez
Bella Vazquez
Vice President of Human Resources

Accepted and Agreed:

/s/ Kate McKinley 05/17/2023
Kate McKinley Date

Portions of this exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted material is of the type that the Registrant treats as private or confidential. Omitted portions are indicated by [*].

Exhibit 31.1

CERTIFICATION

I, Talat Imran, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Rani Therapeutics Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2023

/s/ Talat Imran

Talat Imran

Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Svai Sanford, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Rani Therapeutics Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2023

/s/ Svai Sanford

Svai Sanford

Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Talat Imran, Chief Executive Officer of Rani Therapeutics Holdings, Inc. (the "Company"), and Svai Sanford, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2023, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 11, 2023

In Witness Whereof, the undersigned have set their hands hereto as of the 11th day of August, 2023.

/s/ Talat Imran	/s/ Svai Sanford
Talat Imran	Svai Sanford
Chief Executive Officer	Chief Financial Officer
(Principal Executive Officer)	*(Principal Financial and Accounting Officer)*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Rani Therapeutics Holdings, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.