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, 2024

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 2, 2024, the registrant had 29,290,064 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 1,261,690 shares of the registrant's Class A common stock.

Table of Contents

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").

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 used to date for clinical studies of 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 ability to continue as a going concern;
- 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;
- our ability to realize savings from any restructuring plans or cost-containment measures we propose to implement;
- 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 20, 2024. 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, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 4,514	$ 5,864
Marketable securities	26,387	42,675
Prepaid expenses and other current assets	1,133	2,308
Total current assets	32,034	50,847
Property and equipment, net	5,695	6,105
Operating lease right-of-use asset	5,751	718
Other assets	246	246
Total assets	$ 43,726	$ 57,916
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 506	$ 648
Accrued expenses and other current liabilities	2,422	1,726
Current portion of long-term debt	12,290	4,897
Current portion of operating lease liability	1,363	718
Total current liabilities	16,581	7,989
Long-term debt, less current portion	17,207	24,484
Operating lease liability, less current portion	4,388	—
Total liabilities	38,176	32,473
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Class A common stock, $0.0001 par value - 800,000 shares authorized; 26,489 and 26,036 issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	3	3
Class B common stock, $0.0001 par value - 40,000 shares authorized; 24,116 issued and outstanding as of June 30, 2024 and December 31, 2023	2	2
Class C common stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Additional paid-in capital	90,012	85,762
Accumulated other comprehensive loss	(5)	(12)
Accumulated deficit	(87,177)	(72,889)
Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc.	2,835	12,866
Non-controlling interest	2,715	12,577
Total stockholders' equity	5,550	25,443
Total liabilities and stockholders' equity	$ 43,726	$ 57,916

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,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 6,115	$ 11,086	$ 13,700	$ 20,798
General and administrative	6,409	7,208	12,857	14,012
Total operating expenses	$ 12,524	$ 18,294	$ 26,557	$ 34,810
Loss from operations	(12,524)	(18,294)	(26,557)	(34,810)
Other income (expense), net				
Interest income and other, net	439	896	988	1,787
Interest expense and other, net	(1,276)	(1,266)	(2,571)	(2,473)
Net loss	$ (13,361)	$ (18,664)	$ (28,140)	$ (35,496)
Net loss attributable to non-controlling interest	(6,556)	(9,361)	(13,852)	(17,821)
Net loss attributable to Rani Therapeutics Holdings, Inc.	$ (6,805)	$ (9,303)	$ (14,288)	$ (17,675)
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted	$ (0.26)	$ (0.37)	$ (0.55)	$ (0.70)
Weighted-average Class A common shares outstanding—basic and diluted	26,324	25,345	26,179	25,293

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,	
	2024	2023	2024	2023
Net loss	$ (13,361)	$ (18,664)	$ (28,140)	$ (35,496)
Other comprehensive loss				
Net unrealized gain (loss) on marketable securities	12	(107)	13	19
Comprehensive loss	$ (13,349)	$ (18,771)	$ (28,127)	$ (35,477)
Comprehensive loss attributable to non-controlling interest	(6,550)	(9,415)	(13,845)	(17,811)
Comprehensive loss attributable to Rani Therapeutics Holdings, Inc.	$ (6,799)	$ (9,356)	$ (14,282)	$ (17,666)

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, 2023	26,036	$ 3	24,116	$ 2	$ 85,762	$ (12)	$ (72,889)	$ 12,577	$ 25,443
Issuance of common stock under employee equity plans	175	—	—	—	—	—	—	—	—
Effect of exchanges of non-corresponding Class A Units of Rani LLC	83	—	—	—	—	—	—	—	—
Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC	—	—	—	—	45	—	—	(45)	—
Stock-based compensation	—	—	—	—	1,969	—	—	1,901	3,870
Net loss	—	—	—	—	—	—	(7,483)	(7,296)	(14,779)
Other comprehensive gain	—	—	—	—	—	1	—	—	1
Balance at March 31, 2024	26,294	$ 3	24,116	$ 2	$ 87,776	$ (11)	$ (80,372)	$ 7,137	$ 14,535
Issuance of common stock under employee stock purchase plan, net of shares withheld for tax settlement	110	—	—	—	221	—	—	—	221
Issuance of common stock under employee equity plans, net of shares withheld for tax settlement	85	—	—	—	14	—	—	—	14
Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC	—	—	—	—	(108)	—	—	108	—
Stock-based compensation	—	—	—	—	2,109	—	—	2,020	4,129
Net loss	—	—	—	—	—	—	(6,805)	(6,556)	(13,361)
Other comprehensive gain	—	—	—	—	—	6	—	6	12
Balance at June 30, 2024	26,489	$ 3	24,116	$ 2	$ 90,012	$ (5)	$ (87,177)	$ 2,715	$ 5,550

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

	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

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,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (28,140)	$ (35,496)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	7,999	9,556
Depreciation and amortization	503	377
Non-cash operating lease expense	477	520
Amortization of debt discount and issuance costs	116	116
Net accretion and amortization of investments in marketable securities	(630)	(1,242)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,175	860
Accounts payable	(142)	(332)
Accrued expenses and other current liabilities	688	1,707
Operating lease liabilities	(477)	(521)
Net cash used in operating activities	(18,431)	(24,455)
Cash flows from investing activities		
Proceeds from maturities of marketable securities	38,550	58,000
Purchases of marketable securities	(21,619)	(52,505)
Purchases of property and equipment	(112)	(583)
Net cash provided by investing activities	16,819	4,912
Cash flows from financing activities		
Issuance of common stock under employee stock purchase plan	221	219
Exercise of options	38	—
Proceeds from employee stock purchase plan	27	2
Tax withholdings paid on behalf of employees for net share settlement	(24)	(133)
Net cash provided by financing activities	262	88
Net decrease in cash, cash equivalents and restricted cash equivalents	(1,350)	(19,455)
Cash, cash equivalents and restricted cash equivalents, beginning of period	6,364	27,507
Cash, cash equivalents and restricted cash equivalents, end of period	$ 5,014	$ 8,052
Supplemental disclosures of non-cash investing and financing activities		
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 4,731	$ —
Remeasurement of operating lease right-of-use assets	$ 589	$ 578
Exchanges of non-corresponding Class A Units of Rani LLC	$ 298	$ —
Interest income receivable included in prepaid expenses and other current assets	$ 51	$ 186
Property and equipment purchases included in accounts payable and accrued expenses and other current liabilities	$ —	$ 38

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”, and together with its consolidated subsidiary, 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’s technology comprises a drug-agnostic oral delivery platform, the RaniPill capsule, which is designed to deliver a wide variety of drug substances, including antibodies, proteins, peptides, and oligonucleotides. The Company is advancing a portfolio of oral therapeutics using the RaniPill capsule. The Company is headquartered in San Jose, California and operates in one segment.

Organization

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. In connection with the IPO, the Company effected a series of organizational transactions (the “Organizational Transactions”), which, together with the IPO, were completed in August 2021, that resulted in the Company becoming the ultimate parent company of Rani Therapeutics, LLC (“Rani LLC”). The Company operates its business through Rani LLC.

As part of the Organizational Transactions, the Company entered into a Registration Rights Agreement with certain individuals and entities that continued to hold economic nonvoting Class A units of Rani LLC (“Class A Units”), collectively referred to herein as 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 canceled 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, 2024, 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 1,261,690 shares of the Company’s Class A common stock.

Liquidity

The Company has incurred recurring losses since its inception, including net losses of $28.1 million for the six months ended June 30, 2024. As of June 30, 2024, the Company had an accumulated deficit of $87.2 million and for the six months ended June 30, 2024, had negative cash flows from operations of $18.4 million. As of June 30, 2024, cash, cash equivalents and marketable securities totaled $30.9 million. Based on its available cash resources and current operating plan, there is substantial doubt regarding the Company’s ability to continue as a going concern for a period of one year after the date that its financial statements for the six months ended June 30, 2024 are issued. The Company’s existing capital resources, including the net proceeds from our IPO and term loans (the “Loans”) under a loan and security agreement and related supplement (the “Loan Agreement”) with Avenue Venture Opportunities Fund, L.P (the “Lender”) entered into in August 2022, will not be sufficient to enable it to initiate any pivotal clinical trials. The Company will need to raise substantial additional funds in the future in order to complete the development of the RaniPill platform, to complete the clinical development of its product candidates and seek regulatory approval thereof, to expand its manufacturing capabilities, to further develop the RaniPill HC device and to commercialize any of its product candidates.

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, which may not occur, and approval by the Lender.

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, 2024, the Company has no sales under the Sales Agreement.

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 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. As a result, the Company has concluded that management’s plans do not alleviate substantial doubt about the Company’s ability to continue as a going concern.

Subsequent to June 30, 2024, the Company completed an equity offering with the aggregate gross proceeds of approximately $10.0 million, before deducting placement agent fees and other estimated offering expenses payable by the Company, and excluding potential proceeds, if any, from the exercise of certain warrants issued in the offering (Note 15). The proceeds received do not alleviate substantial doubt about the Company’s ability to continue as a going concern.

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, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024 or for any future period.

The consolidated balance sheet as of December 31, 2023 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 2023 consolidated financial statements and notes included in the Company’s Annual Report on Form 10-K filed with the SEC on March 20, 2024.

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, 2023. Except as noted below, there have been no material changes in the Company's significant accounting policies during the six months ended June 30, 2024.

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, 2024 and 2023:

	Six Months Ended June 30,	
	2024	2023
End of Period:		
Cash and cash equivalents	$ 4,514	$ 7,552
Restricted cash equivalents	500	500
Total cash, cash equivalents and restricted cash equivalents	$ 5,014	$ 8,052

Collaborative Arrangements

The Company assesses whether its collaboration agreements are subject to ASC Topic 808: Collaborative Arrangements based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of Topic 808 and the Company concludes that its collaboration partner is not a customer, the Company presents amounts due from its collaboration partner as a reduction of research and development expense based on the nature of such payments.

Recently Issued Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"). The amendments in ASU 2023-07 are intended to improve reportable segment disclosure, primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for annual periods beginning after December 15, 2023, and interim periods beginning after December 15, 2024. The amendments in this ASU should be applied retrospectively to all prior periods presented in the financial statements. Early adoption is permitted. The Company is evaluating the impact of this guidance on its financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). ASU 2023-09 requires enhanced annual disclosures regarding the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 and may be adopted on a prospective or retrospective basis. Early adoption is permitted. The Company is evaluating the impact of this guidance on its financial statements and related disclosures.

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, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 3,276	$ —	$ —	$ 3,276
Total cash equivalents	3,276	—	—	3,276
Restricted cash equivalents:				
Money market funds	500	—	—	500
Total cash equivalents and restricted cash equivalents	3,776	—	—	3,776
Marketable securities:				
U.S. Treasuries and agencies	24,210	—	(12)	24,198
Corporate debt securities	992	—	(2)	990
Commercial paper	1,200	—	(1)	1,199
Total marketable securities	26,402	—	(15)	26,387
Total cash equivalents, restricted cash equivalents and marketable securities	$ 30,178	$ —	$ (15)	$ 30,163

	As of December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 3,339	$ —	$ —	$ 3,339
Total cash and cash equivalents	3,339	—	—	3,339
Restricted cash equivalents:				
Money market funds	500	—	—	500
Total cash equivalents and restricted cash equivalents	3,839	—	—	3,839
Marketable securities:				
U.S. Treasuries and agencies	35,513	—	(18)	35,495
Corporate debt securities	1,971	—	(8)	1,963
Commercial paper	5,219	—	(2)	5,217
Total marketable securities	42,703	—	(28)	42,675
Total cash equivalents, restricted cash equivalents and marketable securities	$ 46,542	$ —	$ (28)	$ 46,514

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, 2024, 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, 2024. As of each June 30, 2024 and December 31, 2023, interest income receivable recorded as a component of prepaid expenses and other current assets on the condensed consolidated balance sheet was $0.1 million.

4. Fair Value Measurements

The following tables detail 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, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 3,276	$ —	$ —	$ 3,276
Restricted cash equivalents:				
Money market funds	500	—	—	500
Marketable securities				
U.S. Treasuries and agencies	24,198	—	—	24,198
Corporate debt securities	—	990	—	990
Commercial paper	—	1,199	—	1,199
Total assets	$ 27,974	$ 2,189	$ —	$ 30,163

	As of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 3,339	$ —	$ —	$ 3,339
Restricted cash equivalents:				
Money market funds	500	—	—	500
Marketable securities				
U.S. Treasuries and agencies	35,495	—	—	35,495
Corporate debt securities	—	1,963	—	1,963
Commercial paper	—	5,217	—	5,217
Total assets	$ 39,334	$ 7,180	$ —	$ 46,514

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, 2024	December 31, 2023
Accrued professional fees	$ 889	$ 235
Accrued interest	716	500
Payroll and related	271	313
Accrued preclinical and clinical trial costs	12	424
Other	534	254
Total accrued expenses and other current liabilities	$ 2,422	$ 1,726

6. Collaborative Arrangements

ProGen Co., Ltd.

In June 2024, the Company and ProGen Co., Ltd. (“ProGen”) entered into a Collaboration Agreement (the “Collaboration Agreement”). Under the Collaboration Agreement, the Company and ProGen will collaborate to manufacture, develop, seek regulatory approvals for and, if approved, commercialize a product (the “Product”) combining ProGen’s GLP-1/GLP-2 dual agonist compound, PG-102, and the RaniPill HC oral delivery device (the “Device”) in the field of weight management (including without limitation obesity, weight reduction and weight maintenance) in humans (the “Collaboration”).

Under the Collaboration Agreement, development costs, as well as operating profits and losses from the commercialization of the Product, will be equally shared by the Company and ProGen. The Company and ProGen each granted to the other party an exclusive right and license (except with respect to the other party’s affiliates and sublicensees) to certain intellectual property to develop the Product for weight management and an exclusive right and license to seek regulatory approval for, and to use, sell, offer to sell, import and commercialize the Product in their assigned territories. The Company will lead the development of the Product in the United States, Canada, Europe (including the United Kingdom) and Australia, and ProGen will lead development in all other countries.

Each party has the right to opt-out of the Collaboration (“Opt-Out”) at any time upon prior written notice to the other party. Following an Opt-Out, the continuing party shall have sole right to develop, conduct regulatory activities for and commercialize the Product on a worldwide basis. The Opt-Out party shall share all development costs and operating profit (or loss) through the effective date of the Opt-Out, and all costs to complete the conduct of any clinical trials of Product that have been initiated prior to delivery of the Opt-Out notice, even if the costs are incurred or the trials are completed after the effective date of the Opt-Out. The continuing party shall pay to the Opt-Out party low single to mid-single digit royalties on net sales of the Product made after the Opt-Out date depending on when the Opt-Out occurs.

The Company determined that the Collaboration Agreement is not a contract with a customer and is therefore accounted for under ASC Topic 808. The Company evaluates the presentation of amounts due from ProGen based on the nature of each separate activity. Reimbursements from ProGen are recognized as contra-research and development expense on the Consolidated Statement of Operations once earned and collectability is assured. As of June 30, 2024, no reimbursement has been received from ProGen nor recorded as contra-research and development expense.

7. 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.

Service 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 had a term until February 2024, following an extension granted in July 2022, 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 December 2023, Rani LLC provided to ICL notice of termination of the Occupancy Services in San Antonio, which took effect in June 2024. In March 2024, the Company extended the facility in Milpitas, California for an additional six-month term through August 2024 and increased the payment for such Occupancy Services during the extension period.

In June 2021, Rani Management Services, Inc. (“RMS”) entered into a service agreement with ICL 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 agreement. In April 2022, RMS assigned the agreement to Rani LLC. In December 2022, RMS was dissolved. In March 2024, the Company entered into an amendment to increase the Occupancy Services from 23,000 square feet to 24,000 square feet (such agreement, as assigned and amended, the “RMS-ICL Service Agreement”). 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,	
	2024	2023	2024	2023
Research and development	$ 261	$ 299	$ 567	$ 609
General and administrative	97	61	146	133
Total	$ 358	$ 360	$ 713	$ 742

As of June 30, 2024, two of the Company's facilities were owned or leased by an entity affiliated with the Company’s Chairman (Note 8). 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 was three years, which could be extended upon mutual consent of the parties. In June 2024, the parties agreed to extend the term of the Mir Agreement by ninety (90) days.

Tax Receivable Agreement

Certain parties to the tax receivable agreement ("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 ICL and the other Continuing LLC Owners 85% of the amount of tax benefits, if any, it is deemed to realize from exchanges of Paired Interests. During each of the six months ended June 30, 2024 and 2023, these parties to the TRA exchanged zero Paired Interests that resulted in tax benefits subject to the TRA.

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 each of the six months ended June 30, 2024 and 2023, certain related parties that are party to the Rani LLC Agreement exchanged zero Paired Interests for an equal number of shares of the Company's Class A common stock.

8. Leases

In November 2023, Rani LLC and BKM South Bay 240, LLC ("Landlord") entered into the Standard Industrial/Commercial Multi-Tenant Lease - Net (the "Lease"). Pursuant to the terms of the Lease, Rani LLC is leasing approximately 33,000 square feet of space in Fremont, California, which is part of a two-building project (the "Project"). The initial term of the Lease commenced in February 2024, and the duration of the initial term is 63 months. Subject to certain conditions, Rani LLC has an option to renew the Lease for one additional 5-year term at the then-prevailing market rate. The monthly base rent for the initial term of the Lease is approximately $95,000 per month, subject to a 4% increase each year. Rani LLC is also responsible for the payment of additional rent to cover its share of common area operating expenses, including taxes, insurance, utilities, and repair and maintenance of the premises and common areas of the Project.

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. In December 2022, RMS was dissolved. In March 2024, the Company entered into an amendment to increase the Occupancy Services from 23,000 square feet to 24,000 square feet. 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 2024, the Company determined it to be reasonably certain that it would exercise its renewal option for a successive twelve-month period through 2025. 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.

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 a successive twelve-month periods unless terminated; except that the Occupancy Services in Milpitas, California had a term until February 2024, following an extension granted 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 the consolidated balance sheet as of the modification date in July 2022. In December 2023, the Company provided to ICL notice of termination of the Occupancy Services in San Antonio, which took effect in June 2024. In March 2024, the Company extended the facility in Milpitas, California for an additional six-month term through August 2024 and increased the payment for such Occupancy Services during the extension period. As of June 30, 2024, the lease was determined to be short-term.

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. Variable lease payments are excluded in the total operating lease expense and immaterial for the periods presented.

Supplemental information on the Company's condensed consolidated balance sheet and statements of cash flows as of June 30, 2024 and 2023 and for the six months ended June 30, 2024 and 2023, respectively, related to the Company's leases was as follows (in thousands):

	June 30,	
	2024	2023
Weighted-average remaining lease term (in years)	4.3	1.3
Weighted-average discount rate	10.4%	10.4%

	Six Months Ended June 30,	
	2024	2023
Cash paid for amounts included in lease liabilities:		
Operating cash flows used for operating leases	$ 550	$ 521

As of June 30, 2024, minimum annual rental payments under the Company's operating lease agreements are as follows (in thousands), excluding short-term leases:

Year ending December 31,	
2024 (remaining six months)	$ 930
2025	1,902
2026	1,229
2027	1,278
2028	1,330
2029	458
Total undiscounted future minimum lease payments	$ 7,127
Less: Imputed interest	(1,376)
Total operating lease liability	$ 5,751
Less: Current portion of operating lease liability	1,363
Operating lease liability, net current portion	$ 4,388

9. Warrants

In August 2022, in conjunction with a loan and security agreement (Note 12), 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, 2024, there were 76,336 warrants outstanding.

10. Stockholders' Equity

As of June 30, 2024, Rani Holdings held approximately 51% of the Class A Units of Rani LLC, and approximately 49% of the outstanding Class A Units of Rani LLC are held by the Continuing LLC Owners. From the date of the Organizational Transactions to June 30, 2024, 5,173,947 Paired Interests and 283,832 non-corresponding Class A Units of Rani LLC were exchanged for an equal number of shares of the Company's Class A common stock. For each of the six months ended June 30, 2024 and 2023, certain of the Continuing LLC Owners executed an exchange of zero Paired Interests and 83,377 and zero 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 canceled 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 $150.0 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, 2024, the Company had no sales under the Sales Agreement.

11. 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.

Tax Receivable Agreement

The Company is party to a TRA with certain of the Continuing LLC Owners. As of June 30, 2024, 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 $23.1 million at June 30, 2024.

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.

12. Long-Term Debt

In August 2022, the Company 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, which may not occur, 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 (Note 9).

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, which the Company has determined to be not probable as of June 30, 2024. 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, 2024, the effective interest rate on the Loans was 15.62% and there were no events of default during the six months ended June 30, 2024. The Company is also subject to certain covenants. There have been no material adverse events in connection with the Loan Agreement and the substantial doubt regarding our ability to continue as a going concern does not currently constitute a material adverse event under the terms of the Loan Agreement. As of June 30, 2024, the Company was in compliance with all applicable covenants under the Loan Agreement.

As of June 30, 2024, future principal payments for the Company's debt are as follows (in thousands):

Year ending December 31,		
2024 (remaining six months)	$	5,000
2025		15,000
2026		10,000
Total principal payments	$	30,000
Less: amount representing debt discount		(503)
Total long-term debt	$	29,497
Less: current portion of long-term debt		12,290
Total long-term debt, less current portion	$	17,207

13. Income Taxes

The Company's effective income tax rate was zero for each of the six months ended June 30, 2024 and 2023. As a result of the exchanges from the date of the Organizational Transactions to June 30, 2024, the Company recorded a $18.9 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, 2024 and 2023, and the Company does not anticipate material changes within the next twelve months.

14. 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):

	Six Months Ended June 30,	
	2024	2023
Numerator:		
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.	$ (14,288)	$ (17,675)
Denominator:		
Weighted average Class A common share outstanding—basic and diluted	26,179	25,293
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.—basic and diluted	$ (0.55)	$ (0.70)

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,	
	2024	2023
Paired Interests	24,116	24,116
Stock options	10,536	6,414
Non-corresponding Class A Units	1,262	1,387
Restricted stock units	984	1,756
Warrants	76	76
Shares issuable pursuant to the ESPP	41	82
Restricted stock awards	18	51
	37,033	33,882

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, 2024. Therefore, they are not included in the computation of net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.

15. Subsequent Events

Securities Purchase Agreement

In July 2024, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with an institutional investor (the "Equity Investor") relating to the issuance and sale of: (i) 2,800,000 shares of its Class A common stock, par value $0.0001 per share, (ii) pre-funded warrants to purchase 446,753 shares of Class A common stock, (iii) Series A common warrants, which will accompany the Class A common stock and pre-funded warrants, to purchase an aggregate of 3,246,753 shares of Class A common stock and (iv) Series B common warrants, which will accompany the Class A common stock and pre-funded warrants, to purchase an aggregate of 3,246,753 shares of Class A common stock (the "Offering"). The Offering closed on July 23, 2024.

The pre-funded warrants are exercisable immediately following the closing date of the Offering and have an unlimited term and an exercise price of $0.0001 per share. The Series A common warrants will be exercisable following the six-month anniversary of the closing date of the Offering, will expire 18 months from the date of issuance and will have an exercise price of $3.08 per share. The Series B common warrants will be exercisable following the six-month anniversary of the closing date of the Offering, will expire five and a half years from the date of issuance and will have an exercise price of $3.08 per share. The combined offering price is $3.08 per share of Class A common stock and accompanying Series A common warrant and accompanying Series B common warrant, or in the case of pre-funded warrants, $3.0799 per pre-funded warrant and accompanying Series A common warrant and accompanying Series B common warrant. The aggregate gross proceeds to the Company from the Offering were approximately $10.0 million, before deducting placement agent fees and other offering expenses payable by the Company, and excluding potential proceeds, if any, from the exercise of the pre-funded warrants, Series A common warrants and Series B common warrants issued in the Offering.

The Series A common warrants and Series B common warrants include certain rights upon "fundamental transactions" as described in the Series A common warrants and Series B common warrants. In the Series B common warrants, these rights upon "fundamental transactions" include the right of the holders thereof to receive from Rani or a successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of Class A common stock in such fundamental transaction in the amount of the Black Scholes value (as described in such Series B common warrants) of the unexercised portion of the applicable Series B common warrants on the date of the consummation of such fundamental transaction.

Pursuant to the terms of the Securities Purchase Agreement, until 60 days following the closing of the Offering, the Company has agreed not to issue, enter into any agreement to issue, or announce the issuance or proposed issuance of any shares of Class A common stock or common stock equivalents, or file or amend any registration statement or prospectus, other than as necessary to maintain the registration of the securities offered hereby. The Company has further agreed not to enter into an agreement involving any new variable rate transactions until six months following the closing of the Offering, subject to certain exceptions. In addition, the Company's directors and officers have entered into lock-up agreements with the Company pursuant to which each of them has agreed not to, for a period of 60 days from the closing of the Offering, offer, sell, transfer or otherwise dispose of the Company's securities, subject to certain exceptions.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

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, 2023, 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 our Annual Report on Form 10-K for the year ended December 31, 2023. Please also see the section titled "Forward Looking Statements."

The following discussion contains references to calendar year 2023 and the three and six months ended June 30, 2024 and 2023, respectively, which represents the condensed consolidated financial results of Rani Therapeutics Holdings, Inc. (the "Company") and its subsidiary, Rani Therapeutics, LLC ("Rani LLC") for the year ended December 31, 2023 and the three and six months ended June 30, 2024 and 2023, 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 subsidiary.

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 and we are actively pursuing partnering the technology with third party biopharmaceutical companies for the oral delivery of their biologics and drugs.

Our technology comprises a drug-agnostic oral delivery platform, the RaniPill capsule, which is designed to deliver a wide variety of drug substances, including antibodies, proteins, peptides, and oligonucleotides. We are currently developing two configurations of the platform – the RaniPill GO and the RaniPill HC. The RaniPill GO is designed to deliver up to a 3 mg dose of drug in microtablet form with high bioavailability. We have completed three Phase 1 clinical trials using the RaniPill GO. We are also developing a high-capacity version of the RaniPill capsule known as the RaniPill HC, which is intended to enable delivery of drug payloads up to 200µL in liquid form with high bioavailability. We have tested preclinically the RaniPill HC with multiple therapeutics, including antibodies and a peptide. We intend to initiate clinical testing of the RaniPill HC in the second half of 2024.

We believe that, together, the RaniPill GO and RaniPill HC could enable us to deliver most biologics currently on the market with convenient, oral dosing.

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.

As of June 30, 2024, our cash, cash equivalents and marketable securities totaled $30.9 million. In July 2024, we entered into a securities purchase agreement (the “Securities Purchase Agreement”) with an institutional investor relating to the issuance and sale of: (i) 2,800,000 shares of its Class A common stock, (ii) pre-funded warrants to purchase 446,753 shares of Class A common stock, (iii) Series A common warrants, which accompany the Class A common stock and pre-funded warrants, to purchase an aggregate of 3,246,753 shares of Class A common stock and (iv) Series B common warrants, which accompany the Class A common stock and pre-funded warrants, to purchase an aggregate of 3,246,753 shares of Class A common stock (the “Offering”). The aggregate gross proceeds from the Offering were approximately $10.0 million, before deducting placement agent fees and other offering expenses payable by us, and excluding potential proceeds, if any, from the exercise of the pre-funded warrants, Series A common warrants and Series B common warrants issued in the Offering.

We expect to continue to incur 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. Our existing capital resources, including the net proceeds from the recently completed Offering, our initial public offering in 2021 (“IPO”) and term loans we received under a loan and security agreement and related supplement (the “Loan Agreement”) with Avenue Venture Opportunities Fund, L.P (the “Lender”), will not be sufficient to enable us to initiate any pivotal clinical trials. We will need to raise substantial additional funds in the future in order to complete the development of the RaniPill platform, to complete the clinical development of our product candidates and seek regulatory approval thereof, to expand our manufacturing capabilities, to further develop the RaniPill HC device and to commercialize any of our product candidates. We may seek to raise capital through equity offerings or debt financings, collaboration agreements, or other arrangements with other companies, or through other sources of financing.

Pipeline Update

In June 2024, we entered into a definitive agreement (“ProGen Agreement”) with ProGen, Co., Ltd. (“ProGen”) for the co-development and commercialization of RT-114, an oral RaniPill capsule containing ProGen’s PG-102, a GLP-1/GLP-2 dual agonist, for the treatment of obesity. Under the terms of the ProGen Agreement, we and ProGen agree to share responsibilities for the development and commercialization of RT-114 worldwide, including a 50/50 cost and revenue share arrangement. We have exclusive rights to lead development and commercialization of RT-114 in the United States, Europe, Canada and Australia, and ProGen has exclusive rights to lead development and commercialization in the rest of the world. Each party has certain rights to sublicense in its territories. We are designated to lead operationally in conducting preclinical and development activities through the Phase 1 program, which is expected to initiate in 2025. As part of the ProGen Agreement, there was no upfront payment or financial exchange between the companies.

In January 2023, we entered into a License and Supply Agreement with Celltrion Inc. (“Celltrion”) under which we receive a license and supply of Celltrion’s ustekinumab biosimilar for development and commercialization of RT-111 worldwide, subject to a right of first negotiation for Celltrion following completion of a Phase 1 clinical trial that meets its primary endpoint(s). RT-111 is a RaniPill capsule containing our proprietary formulation of an ustekinumab biosimilar. In February 2024, we reported the data for the Phase 1 clinical trial with RT-111 in Australia. The study met all its endpoints, RT-111 was well tolerated and delivered ustekinumab biosimilar with high bioavailability. No serious adverse events were reported in the study. We provided topline data from the study to Celltrion pursuant to the License and Supply Agreement. Celltrion’s right of first negotiation under the License and Supply Agreement has expired.

Relationship with InCube Labs, LLC

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.

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, 2024 and 2023

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

	Three Months Ended June 30,		
	2024	2023	Change
Operating expenses			
Research and development	$ 6,115	$ 11,086	(44.8)%
General and administrative	6,409	7,208	(11.1)%
Total operating expenses	$ 12,524	$ 18,294	(31.5)%
Loss from operations	(12,524)	(18,294)	(31.5)%
Other income (expense), net			
Interest income and other, net	439	896	(51.0)%
Interest expense and other, net	(1,276)	(1,266)	0.8 %
Net loss	$ (13,361)	$ (18,664)	(28.4)%
Net loss attributable to non-controlling interest	(6,556)	(9,361)	(30.0)%
Net loss attributable to Rani Therapeutics Holdings, Inc.	$ (6,805)	$ (9,303)	(26.9)%

Research and Development Expenses

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

	Three Months Ended June 30,	
	2024	2023
Payroll, stock-based compensation and related benefits	$ 4,677	$ 7,617
Facilities, materials and supplies	1,217	1,603
Third-party services	205	1,764
Other	16	102
Total	$ 6,115	$ 11,086

The decrease of $5.0 million in research and development expenses in the three months ended June 30, 2024, as compared to the same period in 2023, was primarily attributed to lower compensation costs of $2.9 million due to reduction in workforce, $1.6 million reduction in third-party services and $0.4 million reduction in materials and supplies due to the timing of certain preclinical and clinical studies.

General and Administrative Expenses

The decrease of $0.8 million in general and administrative expenses in the three months ended June 30, 2024, as compared to the same period in 2023, was primarily attributed to lower compensation costs of $1.3 million due to reduction in workforce, offset by an increase in facility costs of $0.4 million due to the lease in Fremont, California.

Other Income (Expense), Net

The increase of $0.5 million in other expense, net, in the three months ended June 30, 2024, as compared to the same period in 2023, was attributed to a decrease in interest income of $0.5 million from our investment in marketable securities.

Comparison of the six months ended June 30, 2024 and 2023

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

	Six Months Ended June 30,		
	2024	2023	Change
Operating expenses			
Research and development	$ 13,700	$ 20,798	(34.1)%
General and administrative	12,857	14,012	(8.2)%
Total operating expenses	$ 26,557	$ 34,810	(23.7)%
Loss from operations	(26,557)	(34,810)	(23.7)%
Other income (expense), net			
Interest income and other, net	988	1,787	(44.7)%
Interest expense and other, net	(2,571)	(2,473)	4.0 %
Net loss	$ (28,140)	$ (35,496)	(20.7)%
Net loss attributable to non-controlling interest	(13,852)	(17,821)	(22.3)%
Net loss attributable to Rani Therapeutics Holdings, Inc.	$ (14,288)	$ (17,675)	(19.2)%

Research and Development Expenses

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

	Six Months Ended June 30,	
	2024	2023
Payroll, stock-based compensation and related benefits	$ 10,425	$ 14,988
Facilities, materials and supplies	2,600	3,052
Third-party services	648	2,621
Other	27	137
Total	$ 13,700	$ 20,798

The decrease of $7.1 million in research and development expenses in the six months ended June 30, 2024, as compared to the same period in 2023, was primarily attributed to lower compensation costs of $4.6 million due to reduction in workforce, $2.0 million reduction in third-party services and $0.4 million reduction in materials and supplies due to the timing of certain preclinical and clinical studies.

General and Administrative Expenses

The decrease of $1.2 million in general and administrative expenses in the six months ended June 30, 2024, as compared to the same period in 2023, was primarily attributed to lower compensation costs of $1.5 million due to reduction in workforce and $0.3 million reduction in other costs, offset by an increase in facility costs of $0.5 million due to the lease in Fremont, California.

Other Income (Expense), Net

The increase of $0.9 million in other expense, net, in the six months ended June 30, 2024, as compared to the same period in 2023, was primarily attributed to a decrease in interest income of $0.8 million from our investment in marketable securities and an increase interest expense of $0.1 million from our debt.

Liquidity and Capital Resources

Overview

We have incurred recurring losses and negative cash flows from operations since inception, including net loss of $28.1 million for six months ended June 30, 2024. As of June 30, 2024, we had an accumulated deficit of $87.2 million and for six months ended June 30, 2024, had negative cash flows from operations of $18.4 million. As of June 30, 2024, our cash, cash equivalents and marketable securities totaled $30.9 million. We expect to continue to incur 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. Our existing capital resources, including the net proceeds from our IPO and term loans we received under the Loan Agreement, will not be sufficient to enable us to initiate any pivotal clinical trials. Based on our available cash resources and current operating plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the six months ended June 30, 2024 are issued. If we are unable to continue as a going concern, we may have to cease operations and liquidate our assets. We may receive less than the value at which those assets are carried on our condensed consolidated financial statements, and investors may lose all or a part of their investment.

Financial Update

In July 2024, we entered into the Securities Purchase Agreement with an institutional investor relating to the Offering. The aggregate gross proceeds from the Offering were approximately $10.0 million, before deducting placement agent fees and other offering expenses payable by us, and excluding potential proceeds, if any, from the exercise of the pre-funded warrants, Series A common warrants and Series B common warrants issued in the Offering.

Pursuant to the terms of the Securities Purchase Agreement, until 60 days following the closing of the Offering, we have agreed not to issue, enter into any agreement to issue, or announce the issuance or proposed issuance of any shares of Class A common stock or common stock equivalents, or file or amend any registration statement or prospectus, other than as necessary to maintain the registration of the securities offered hereby. We have further agreed not to enter into an agreement involving any new variable rate transactions until six months following the closing of the Offering, subject to certain exceptions.

In November 2023, we committed to a plan for strategic prioritization of our programs, expansion of our manufacturing and streamlining of our business operations to support potential near-term value drivers and long-term growth (the “Restructuring”). The Restructuring included a reduction of our workforce by approximately 25%. As a result of the Restructuring, we incurred $0.3 million in costs of which nearly all are cash expenditures related to severance. The Restructuring was substantially completed by the end of the second quarter of 2024.

In November 2023, our Board of Directors (the “Board”) approved a reduction in the annual salary of Talat Imran, our Chief Executive Officer, from $520,000 to $100,000, effective November 1, 2023 through December 31, 2024 or until such time as we receive gross proceeds of $50,000,000 or more, in the aggregate, from equity financing and/or one or more non-dilutive strategic, licensing or partnering transactions. The decreased base salary amends the Amended and Restated Employment Agreement, dated August 31, 2022, by and between Rani LLC and Mr. Imran.

In August 2022, we entered into the Loan Agreement with 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, which may not occur, and approval by the Lender. The Loan Agreement also contains various covenants and restrictive provisions. There have been no material adverse events in connection with the Loan Agreement and the substantial doubt regarding our ability to continue as a going concern does not currently constitute a material adverse event under the terms of the Loan Agreement. The Loan principal is repayable in equal monthly installments beginning September 2024 extendable to March 2025 under certain conditions, which the Company has determined to be not probable as of June 30, 2024. As of June 30, 2024, we were in compliance with all applicable debt covenants under the Loan Agreement.

In August 2022, we 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 we may offer and sell from time to time through the Agents up to $150.0 million of shares of its 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. The potential proceeds from the Sales Agreement are expected to be used for general corporate purposes. As of June 30, 2024, we had no sales under the Sales Agreement.

Tax Receivable Agreement

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.

Future Funding Requirements

Notwithstanding the sharing of development costs for the RT-114 program under the ProGen Agreement, our existing capital resources, including the net proceeds from our IPO, Loans and the Offering, will not be sufficient to enable us to initiate any pivotal clinical trials with respect to any of our product candidates. We will need to raise substantial additional funds in the future in order to complete the development of the RaniPill platform, to complete the clinical development of our product candidates and seek regulatory approval thereof, to expand our manufacturing capabilities, to further develop the RaniPill HC device and to commercialize any 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.

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 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;
- our ability to realize savings from any restructuring plans or cost-containment measures we may implement; and
- the economic and other terms, timing of and success of any collaboration, licensing, or other arrangements which we may enter in the future.

Pursuant to the terms of the Securities Purchase Agreement, until 60 days following the closing of the Offering, we agreed not to issue, enter into any agreement to issue, or announce the issuance or proposed issuance of any shares of Class A common stock or common stock equivalents, or file or amend any registration statement or prospectus, other than as necessary to maintain the registration of the securities offered in the Offering. We further agreed not to enter into an agreement involving any new variable rate transactions until six months following the closing of the Offering, subject to certain exceptions. These restrictions could prevent us from raising additional capital that we might otherwise be able to raise.

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. Furthermore, this Quarterly Report on Form 10-Q contains statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all.

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

	June 30, 2024	December 31, 2023
Cash and cash equivalents	$ 4,514	$ 5,864
Marketable securities	26,387	42,675
Total cash, cash equivalents and marketable securities	$ 30,901	$ 48,539

As of June 30, 2024, we had cash and cash equivalents and marketable securities of $30.9 million, compared to $48.5 million as of December 31, 2023. Based on our available cash resources and current operating plan, there is substantial doubt regarding our ability to continue as a going concern for a period of one year after the date that our financial statements for the six months ended June 30, 2024 are issued. Our existing capital resources, including the net proceeds from our IPO and Loans, will not be sufficient to fund our projected operating requirements for a twelve-month period from the issuance of our financial statements.

Cash Flows

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

	Six Months Ended June 30,	
	2024	2023
Net cash used in operating activities	$ (18,431)	$ (24,455)
Net cash provided by investing activities	16,819	4,912
Net cash provided by financing activities	262	88
Net decrease in cash, cash equivalents and restricted cash equivalents	$ (1,350)	$ (19,455)

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2024 was $18.4 million, which was primarily attributable to a net loss of $28.1 million and net accretion and amortization of investments in marketable securities of $0.6 million, partially offset by the stock-based compensation expense of $8.0 million and depreciation and amortization expense of $0.5 million. Additionally, there was a decrease of $1.2 million in prepaid expenses and other current assets and an increase in accrued expenses and other current liabilities of $0.7 million for the six months ended June 30, 2024.

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 and net accretion and amortization of investments in marketable securities of $1.2 million, partially offset by stock-based compensation expense of $9.6 million and 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.

Investing Activities

For the six months ended June 30, 2024, net cash provided by investing activities was $16.8 million, which primarily consisted of $38.6 million in proceeds from maturities of marketable securities partially offset by $21.6 million in purchases of marketable securities.

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.

Financing Activities

For the six months ended June 30, 2024, net cash provided by financing activities was $0.3 million, which primarily consisted of the issuance of common stock under employee stock purchase plan.

For the six months ended June 30, 2023, net cash provided by financing activities was de minimis.

Contractual Obligations and Other Commitments

As of June 30, 2024, there have been no material changes to our contractual obligations and other commitments compared to those disclosed in our Annual Report on Form 10-K

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, 2023, filed with the SEC on March 20, 2024.

Recently Adopted Accounting Standards

See Note 2 to the condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

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 IPO), (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, 2024.

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, 2024 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, 2023.

Our collaboration agreement with ProGen Co., Ltd. includes certain restrictions and obligations that may limit our flexibility in developing and commercializing RT-114 or require us to bear costs we otherwise would not incur.

In June 2024, we entered into a Collaboration Agreement with ProGen for the worldwide development and commercialization of RT-114, a GLP-1/GLP-2 dual agonist in the RaniPill® HC capsule. Under the terms of the ProGen Agreement, the parties will share equally the costs and revenues from development and commercialization of RT-114. Each party has certain rights, restrictions and obligations under the ProGen Agreement with respect to the development, manufacture and commercialization of RT-114, including certain rights to provide input on or approve activities of the other party or costs related thereto. As a result, we may not be able to develop and commercialize RT-114 in the manner or timeframe we believe to be most advantageous, and may be obligated to share costs that we otherwise would not incur. In addition, under the terms of the ProGen Agreement, each party has the right to opt-out of the collaboration, including the cost and revenue sharing, for RT-114, in which case the continuing party would bear all costs for further development, manufacture and commercialization of RT-114, other than certain costs already then-approved, and receive all future revenues from the program, subject to a low-to-mid single-digit royalty to the other party, depending on when the opt-out occurred. If ProGen were to opt-out, we would bear all such costs for further development, manufacture and commercialization of RT-114.

Negative results arising from ProGen's development or future commercialization of PG-102, the therapeutic compound used in RT-114, could have materially adverse effects on our development of RT-114, or limit the commercial profile of an approved label for or result in limiting the commercial opportunity for RT-114, if approved..

The therapeutic compound utilized in RT-114 is a GLP-1/GLP-2 dual agonist from ProGen known as PG-102. ProGen is developing PG-102, independent of our collaboration, as a subcutaneous injection for obesity and type-II diabetes. ProGen may develop PG-102 for other indications. ProGen's PG-102 is in Phase 1 clinical testing. If ProGen's clinical or preclinical testing of PG-102 results in data that is negative, or perceived to be negative, including without limitation safety concerns, adverse events or uncompetitive or poor efficacy data, or if ProGen encounters challenges obtaining regulatory approval for or commercial success with PG-102, such results could materially adversely affect the development, potential for regulatory approval for and/or commercial opportunity of RT-114, since RT-114 utilizes the same compound. In addition, if ProGen, itself or through a partner, succeeds in developing, obtaining regulatory approval for, and commercializing PG-102 outside of our collaboration, that product could compete with RT-114 and have a material adverse effect on the commercial opportunity for RT-114.

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).
10.1*x	Collaboration Agreement between Rani Therapeutics, LLC and ProGen Co., Ltd. dated June 17, 2024.
10.2*	Extension of Intellectual Property Agreement dated June 12, 2024 by and between Rani Therapeutics, LLC and Mir Imran.
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.

† 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 6, 2024

By: /s/ Talat Imran

Talat Imran

Chief Executive Officer

(Principal Executive Officer)

Date: August 6, 2024

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 [*].

Execution

Collaboration Agreement

By and Between

Rani Therapeutics, LLC

and

ProGen Co., Ltd.

Dated

June 17, 2024

CONFIDENTIAL

Collaboration Agreement

Preamble

This Collaboration Agreement (this *"Agreement"*), effective as of June 17, 2024, is by and between Rani Therapeutics, LLC, a California limited liability company having its principal place of business at 2051 Ringwood Ave., San Jose, California 95131, USA (*"Rani"*), and ProGen Co., Ltd., a Korean corporation having its principal place of business at 172, Magokjungang-ro, Gangseo-gu, Seoul, 07789 Republic of Korea (*"ProGen"*). Rani and ProGen are sometimes referred to herein individually as a *"Party"* and collectively as the *"Parties."*

Recitals

WHEREAS, Rani has developed oral delivery technology to enable oral administration of biologics and drugs;

WHEREAS, ProGen is developing a compound referred to as PG-102 that binds GLP-1 and GLP-2 for the treatment of obesity and metabolic conditions;

WHEREAS, the Parties desire to collaborate in the development and commercialization of a product combining ProGen's PG-102 compound and Rani's oral delivery technology in the Field in the Territory (each as defined below) in accordance with the terms and conditions hereof;

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. *"Accounting Standards"* means internationally recognized accounting principles (including IFRS, US GAAP, and the like), in each case, as then in effect and as consistently applied by the applicable Party or its Affiliate or Sublicensee.

1.2. *"Affiliate"* means, with respect to a Person, any Person which controls, is controlled by or is under common control with such first Person. 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. Notwithstanding the foregoing, [*] and its direct and indirect subsidiaries shall be deemed to be Affiliates of [*], and only [*] and its direct and indirect subsidiaries shall be deemed to be Affiliates of [*].

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

1.4. *"Alliance Managers"* has the meaning set forth in Section 2.2.5 (Alliance Managers).

1.5. *"Annual Development Budget"* means, with respect to a given Calendar Year, the amount apportioned in the Development Budget for Development of Product in the Field for such Calendar Year, as such budget may be revised from time to time by the JCC.

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

1.7. *"Approved Business Case"* has the meaning set forth in Section 5.2 (Business Case).

1.8. *"Approved Party"* means [*] and its subsidiaries.

1.9. *"Background IP"* means any intellectual property rights that a Party has lawfully (i) owned or been licensed to use prior to the signing of the Agreement, or (ii) acquired independently of the Collaboration and of the performance of the Development, Manufacture or Commercialization of the Product under this Agreement, even if such intellectual property is used in or for the Collaboration or the Development, Manufacture or Commercialization of the Product under this Agreement.

1.10. *"*[*]*"* means [*].

1.11. *"Bundle"* has the meaning set forth in Exhibit D (Operating Profit or Loss Calculation).

1.12. *"Business Case"* has the meaning set forth in Section 5.2 (Business Case).

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

1.14. *"Calendar Quarter"* means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31.

1.15. *"Calendar Year"* means each respective period of twelve (12) consecutive months ending on December 31.

1.16. *"Change of Control"* means, (i) the acquisition, directly or indirectly, by any person, entity or "group" (within meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended) by means of a transaction or series of related transactions, of (a) beneficial ownership of fifty percent (50%) or more of the outstanding Voting Securities of a Party (or the surviving entity, as applicable, whether by merger, consolidation, reorganization, tender offer or other similar means), or (b) all, or substantially all, of the assets of a Party and its Affiliates; or (ii) any consolidation or merger of a Party with or into any Third Party, or any other corporate reorganization involving a Third Party, in which those persons or entities that are stockholders of the Party immediately prior to such consolidation, merger or reorganization (or prior to any series of related transactions leading up to such event) own fifty percent (50%) or less of the surviving entity's voting power immediately after such consolidation, merger or reorganization. Notwithstanding the foregoing, any transaction or series of transactions effected for the purpose of financing the operations of the applicable Party or one or more of its applicable Affiliates (such as an initial public offering or other offering of equity securities to investors) shall not be deemed a "Change of Control" for purposes of this Agreement.

1.17. *"Claims"* has the meaning set forth in Section 14.1 (Indemnity).

1.18. *"CMO"* means a Third Party contract manufacturing organization.

1.19. *"Co-Chair"* has the meaning set forth in Section 2.2.2 (Composition).

1.20. *"Collaboration"* has the meaning set forth in Section 2.1 (Conduct of the Collaboration).

1.21. *"Commercialization"* means the conduct of all activities undertaken before and after Regulatory Approval relating to the promotion, marketing, sale and distribution (including importing, exporting, transporting, customs clearance, warehousing, invoicing, handling and delivering products to customers) of products, including: (i) sales force efforts, detailing, advertising, medical education, planning, marketing, sales force training, and sales and distribution; (ii) scientific and medical affairs; and (iii) pricing, access and reimbursement activities. For clarity, Commercialization does not include any Development activities, whether conducted before or after Regulatory Approval. "*Commercialize*" and "*Commercializing*" have correlative meanings.

1.22. *"Commercialization Budget"* means a budget agreed by the Parties covering the activities contemplated in the Commercialization of the Product, as such budget may be revised from time to time by the JCC.

1.23. *"Commercialization Costs"* means costs and expenses incurred by a Party or any of its Affiliates in accordance with applicable Accounting Standards during the Term of this Agreement that are specifically attributable or reasonably allocable to the Commercialization of Product by such Party or any of its Affiliates and that are incurred in connection with the applicable Commercialization Plan. Commercialization Costs shall include both internal FTE Costs and Out-of-Pocket Costs of obtaining outside services and materials

and conducting outside activities. Commercialization Costs shall also include costs and expenses incurred by a Party or any of its Affiliates that are directly related to (a) the cost of obtaining sales and marketing data and detailing the Product, (b) scientific and medical affairs activities, and (c) value and access activities to support pricing or reimbursement of Product. Notwithstanding anything to the contrary in the foregoing, Commercialization Costs shall specifically exclude the cost and expense of activities that promote a Party's business as a whole that are not specific to the Product (e.g., corporate image advertising).

1.24. *"Commercialization Plan"* has the meaning set forth in Section 5.4 (Commercialization Plan and Reporting).

1.25. *"Commercially Reasonable Efforts"* means, with respect to efforts to be expended by a Party hereunder, those efforts and resources commensurate with those efforts commonly used in the pharmaceutical industry by a company of comparable stage and size of the applicable Party in connection with the Development, regulatory, Manufacturing and Commercialization activities of pharmaceutical products that are of similar status to the Product, taking into account relative safety and efficacy, product profile, the regulatory path and environment, commercial potential, payors' policies and regulations, competitiveness of the marketplace, the nature and extent of market exclusivity, including patent coverage and regulatory data protection, price and reimbursement status, and all other relevant commercial, technical, legal, scientific, regulatory, or medical factors. In determining the level of efforts constituting *"Commercially Reasonable Efforts"*, [*].

1.26. *"Compound"* means the GLP-1/GLP-2 dual agonist compound being developed by ProGen and referred to as PG-102, and [*].

1.27. *"Compound Manufacturing Data"* means data related to the Manufacture of the Compound but not related to the Manufacture of Device or Product.

1.28. *"Compound-Specific Data"* means data generated in the conduct of the Development, Manufacture or Commercialization of the Product or other Collaboration activities, that are related to the Compound but not related to the Oral Delivery Technology or the combination of the Compound with the Oral Delivery Technology.

1.29. *"Confidential Information"* has the meaning set forth in Section 11.1 (Confidentiality; Exceptions).

1.30. *"Consensus Matters"* means [*].

1.31. *"Continuing Party"* has the meaning set forth in Section 11.2 (Effects of Opt-Out).

1.32. *"Continuing Party Net Sales"* has the meaning set forth in Exhibit E (Royalties).

1.33. *"Continuing Seller"* has the meaning set forth in Exhibit E (Royalties).

1.34. *"Contract Interest Rate"* means [*] plus the U.S. prime rate effective for the date that payment was due, as published by The Wall Street Journal, Eastern U.S. Edition, on the date such payment was due (or, if unavailable on such date, the first date thereafter on which such rate is available), or, if lower, the maximum rate permitted by Applicable Law.

1.35. "*Control*" or "*Controlled*" means, with respect to any Information or intellectual property, that the applicable Party or its Affiliates has the legal authority or right (whether by ownership, license or otherwise, other than by virtue of any license granted to such Party by the other Party pursuant to this Agreement) to grant a license, sublicense, access or other right (as applicable) under such Information or intellectual property to the other Party on the terms and conditions set forth herein as of the time such Party would first be required hereunder to grant such access, license, sublicense or other right, in each case without violating the terms of any agreement with a Third Party or requiring any payment (whether or not then due and payable) unless the other Party agrees in writing to be responsible for such payments or such payment is subject to cost-sharing under Section 7.1 (Development Costs) or to Section 7.2 (Operating Profit (or Loss)). If a Party undergoes a Change of Control, the acquiring Person and its affiliates prior to a Change of Control shall not be deemed "Affiliates" of the acquired Party for purposes of this definition of Control (or Controlled).

1.36. *"Core Dossier"* has the meaning set forth in Section 4.2 (Core Dossier).

1.37. *"Cover", "Covered" or "Covering"* means, with respect to a product and a Patent, that, in the absence of a (sub)license under, or ownership of, such Patent, the making, using, offering for sale, selling or importing of such product with respect to a given country would infringe a Valid Claim of such Patent.

1.38. "*Debar*", "*Debarred*" or "*Debarment*" means (a) being debarred, or being subject to a pending debarment, pursuant to section 306 of the FDCA, 21 U.S.C. § 335a, (b) being listed by any federal and/or state agencies, excluded, debarred, suspended or otherwise made ineligible to participate in federal or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)), or being subject to any pending process by which any such listing, exclusion, debarment, suspension or other ineligibility could occur, (c) being disqualified by any government or regulatory agency from performing specific services, or being subject to a pending disqualification proceeding, (d) being convicted of a criminal offense related to the provision of healthcare items or services or being subject to any pending criminal action related to the provision of healthcare items or services, (e) being subject to US Department of the Treasury's Office of Foreign Asset Control ("*OFAC*") sanctions or on the OFAC list of specially designated nationals or foreign sanctions evaders, (f) being subject to the US Department of Commerce's Bureau of Industry and Security's Entity List or Unverified List, or (g) the subject of any similar proceedings or sanction of any governmental authority in any jurisdiction.

1.39. "*Develop*" or "*Development*" means to develop (including preclinical, clinical, non-clinical and CMC development), analyze, test and conduct preclinical and clinical studies and all other regulatory trials for a product, including all post-approval clinical trials, as well as all related regulatory activities and any and all activities pertaining to new indications, pharmacokinetic studies and all related activities including CMC activities. "Developing" and "Development" have correlative meanings.

1.40. *"Development Budget"* means a multi-year budget agreed by the Parties covering the activities contemplated in the Development Plan for the Product, as such budget may be revised from time to time by the JCC. The initial version of the Development Budget is set forth on Exhibit B.

1.41. *"Development Costs"* means, with respect to Product, Shared Manufacturing Expenses and a Party's (and its Affiliates') worldwide Out-of-Pocket Costs specifically attributable to Development of the Product in the Field in accordance with the Development Plan, including to obtain, maintain and expand Regulatory Approvals for the Product, as more specifically set forth in the Exhibit C (Development Costs).

1.42. *"Development Plan"* means a multi-year development plan for the Product in the Field in the Territory, the initial version of which is set forth on Exhibit A, as such development plan may be updated and approved by the JCC from time to time.

1.43. *"Device"* means the RaniPill™ HC (high capacity) oral delivery device and any improvements thereto.

1.44. *"Direct Expenses"* means Out-of-Pocket Costs for those material and services expenses captured in invoices and the like which are specifically attributable to the Manufacture of Product, including expenses of raw materials, Manufacturing supplies, solvents, containers, container components, packaging, labels and other printed materials used in production.

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

1.46. *"EMA"* means the European Medicines Agency, and any successor agency thereto.

1.47. *"EU"* means those countries, nations, states or other territories under the jurisdiction of the EMA, as such jurisdiction may change from time to time.

1.48. *"Excluded Party"* means [*], together with its affiliates, [*].

1.49. *"Exclusive Activities"* has the meaning set forth in Section 8.7 (Exclusivity).

1.50. *"FDA"* means the US Food and Drug Administration, and any successor agency thereto.

1.51. *"Field"* means the field of weight management (including without limitation obesity, weight reduction and weight maintenance) in humans. The Parties may broaden the Field to include additional indications upon

mutual agreement. For clarity, the initial Field does not include diabetes or metabolic dysfunction-associated steatohepatitis (MASH).

1.52. *"First Commercial Sale"* means the first commercial sale of Product in the applicable country or territory by or under the authority of a Party or its Affiliate or Sublicensee to a Third Party for consumption by an end user after receipt of the applicable Regulatory Approval.

1.53. *"FTE"* means the equivalent of the work of one employee full time for one year (consisting of at least a total of [*] weeks or [*] hours per year (excluding vacations and holidays)). Overtime, and work on weekends, holidays and the like shall not be counted with any multiplier (e.g., time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution.

1.54. *"FTE Costs"* means the product of: (a) that number of FTEs (proportionately, on a per-FTE basis) used by a Party or its Affiliates in directly performing the applicable Collaboration or Manufacturing activities, multiplied by (b) the applicable FTE Rate. For clarity, FTE Costs do not include costs of recruiting, hiring or terminating FTEs.

1.55. *"FTE Rate"* means the hourly rate for FTE time set forth on Exhibit K, increasing by [*] each subsequent Calendar Year, unless otherwise agreed by the Parties. The FTE Rate includes costs associated with salaries, payroll taxes, bonuses, benefits, recruiting, relocation, employee stock option programs or stock grants, retirement programs, and applicable overhead (e.g., facilities, operating supplies, travel and training).

1.56. *"*[*]*"* has the meaning set forth in Section 8.7 (Exclusivity).

1.57. *"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.

1.58. *"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.

1.59. *"Indemnified Party"* has the meaning set forth in Section 14.2 (Claim for Indemnification).

1.60. *"Indemnifying Party"* has the meaning set forth in Section 14.2 (Claim for Indemnification).

1.61. *"Indirect Expenses"* means, with respect to Compound, Device or Product, labor expenses, including allocated FTE Costs for personnel directly involved in Manufacturing Compound, Device or Product, as applicable, in accordance with applicable regulatory requirements such as production, quality control, quality assurance, and other similar departments as needed and to the extent such personnel participate directly in the production of the Compound, Device or Product, as applicable, and components thereof, and other indirect production expenses such as a reasonable allocation of expenses associated with a Party's Manufacture of Compound, Device or Product, as applicable, including facility costs and FTE Costs directly supporting the Manufacturing of Compound, Device or Product, as applicable, in accordance with applicable regulatory requirements, including labor for and indirect expenses of quality control, quality assurance, raw material acquisition and acceptance, microbiology, document control, calibration/validation, and expenses for process development and analytical methods development, but excluding, in each case, any Direct Expenses.

1.62. *"Information"* means all techniques, information, technology, practices, trade secrets, inventions (whether patentable or not), methods, processes, 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, drawings, designs, software and algorithms. *"Information"* excludes tangible materials, including biological compounds, chemical compounds and reagents, Devices and components thereof.

1.63. *"Initiation"* of a clinical trial or to *"Initiate"* a clinical trial means the first dosing of a human subject with the active product (not placebo) in such trial.

1.64. *"Insolvency Event"* means, with respect to any Party, the occurrence of any of the following: (a) such Party shall commence a voluntary case concerning itself under any bankruptcy, liquidation or insolvency code; (b) an involuntary case is commenced against such Party and the petition is not dismissed within sixty (60) days after commencement of the case; (c) a court-supervised custodian is appointed for, or takes charge of, all or substantially all of the property of such Party or such Party commences any other proceedings under any reorganization, arrangement, adjustment of debt, relief of debtors, dissolution, insolvency or liquidation or similar law of any jurisdiction whether now or hereafter in effect relating to such Party or there is commenced against such Party any such proceeding which remains undismissed for a period of sixty (60) days; (d) any order of relief or other order approving any such case or proceeding is entered; (e) such Party is adjudicated insolvent or bankrupt; (f) such Party suffers any appointment of any court-appointed custodian, receiver or the like for it or all or substantially all of its property which continues undischarged or unstayed for a period of sixty (60) days; or (g) such Party makes a general assignment for the benefit of creditors.

1.65. *"Joint Collaboration Committee"* or *"JCC"* means the collaboration steering committee established pursuant to Article 2 (Collaboration Scope and Governance).

1.66. *"Joint Patent Rights"* means the Patent Rights jointly owned by the Parties with respect to Joint Program Inventions.

1.67. *"Joint Program Activities"* means any activities with respect to Product conducted by either Party or any of its Affiliates, Sublicensees or Subcontractors during the Term consisting of (a) Development of the Product in accordance with the Development Plan, including for the purpose of, or in support of, obtaining, maintaining or expanding Regulatory Approval for Product in the Territory in accordance with the Development Plan, (b) Commercialization of the Product in the Field in such Party's Licensed Territories in accordance with the Commercialization Plan for the Product in such territory, or (c) the Manufacture of the Product for use in any of the activities set forth under clause (a) or (b).

1.68. *"Joint Program Damages"* means any Losses (including reasonable legal expenses and attorneys' fees) incurred in connection with any Third Party Claims that arise from or are related to [*], *other than* any such items to the extent arising out of (a) any breach of, or inaccuracy in, any representation or warranty made by a Party in this Agreement, or any breach or violation of any covenant or agreement of a Party in this Agreement, or (b) the gross negligence or willful misconduct by or of a Party or any of its respective Affiliates or any of their respective directors, officers, employees or agents in the performance of such Party's obligations or exercise of its rights under this Agreement.

1.69. *"Joint Program Inventions"* has the meaning set forth in Section 9.2.4 (Joint Program Inventions).

1.70. *"Licensed IP"* means, with respect to a Party, the Patent Rights and Information licensed by such Party to the other Party under Section 8.1 (License to ProGen) and 8.2 (License to Rani).

1.71. *"Licensed ProGen Know-How"* means Information Controlled, as of the Effective Date or thereafter during the Term, by ProGen or its Affiliates (including Program Inventions) that are necessary or reasonably useful for the Development, Manufacture or commercialization of the Product in the Field.

1.72. *"Licensed ProGen Patents"* means those patents and patent applications set forth on Exhibit H, as well as any continuation, divisional, substitution, continuations-in-part, reissue, reexamination, provisional and converted provisional application thereof, as well as any Patent in the Territory Controlled by ProGen or its Affiliates on or after the Effective Date, in each case that (a) would (absent the licenses granted herein) be infringed by the Development, Manufacture or Commercialization of Product in the Field in the Territory or (b) would be necessary or reasonably useful for the Development, Manufacture or Commercialization of Product in the Field in the Territory. For purposes of determining whether a patent application falls within clause (a) 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.

1.73. *"Licensed Rani Know-How"* means Information Controlled, as of the Effective Date or thereafter during the Term, by Rani or its Affiliates (including Program Inventions) that are necessary or reasonably useful for the Development, Manufacture or commercialization of the Product in the Field.

1.74. *"Licensed Rani Patents"* means those patents and patent applications set forth on Exhibit I, as well as any continuation, divisional, substitution, continuations-in-part, reissue, reexamination, provisional and converted provisional application thereof, as well as any Patent in the Territory Controlled by Rani or its Affiliates on or after the Effective Date, in each case that (a) would (absent the licenses granted herein) be infringed by the Development, Manufacture or Commercialization of Product in the Field in the Territory or (b) would be necessary or reasonably useful for the Development, Manufacture or Commercialization of Product in the Field in the Territory. For purposes of determining whether a patent application falls within clause (a) 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.

1.75. *"Licensed Territory"* means, with respect to a Party, a country or territory assigned to such Party under the Agreement for the Development and Commercialization of Product in the Field. The Licensed Territories for each Party are set forth in Exhibit F.

1.76. *"Licensee"* means a Party in its capacity as the recipient of the license granted under Section 8.1 (License to ProGen) or 8.2 (License to Rani), as applicable.

1.77. *"Licensor"* means a Party in its capacity as the granting party of the license granted under Section 8.1 (License to ProGen) or 8.2 (License to Rani), as applicable.

1.78. *"Losses"* means liabilities, losses, costs, damages, fees or expenses.

1.79. *"Major Markets"* means the United States of America, the EU, the United Kingdom, Canada, Australia, Japan and South Korea.

1.80. *"Manufacture"* or *"Manufacturing"* means performing all steps of the manufacturing of the Compound, Device or Product, as applicable, including: (i) acquisition, testing and release of raw materials, excipients or active pharmaceutical ingredients and stability testing; (b) manufacturing and filling; (c) Device assembly; (d) in-process quality control testing; (e) labeling and packaging; (f) final quality release; and (g) storage prior to shipping and the related controls.

1.81. *"Manufacturing Expenses"* means (a) with respect to Compound, Device or Product, as applicable, that is Manufactured by a Third Party CMO, the amount paid by either Party or its Affiliate to such Third Party for such Compound, Device or Product, and (b) with respect to Compound, Device or Product that is Manufactured directly by either Party or its Affiliate the Direct Expenses and Indirect Expenses incurred by such Party or its Affiliate in connection with the Manufacture of the Compound, Device or Product. Unless otherwise determined by the JCC, Manufacturing Expenses shall not include any: (w) capital expenditures, (x) Manufacturing variances due to idle plant capacity, (y) expenses allocable to other products, or (z) any profit related to intercompany transfer pricing.

1.82. *"*[*]*"* means [*].

1.83. *"*[*] *Agreement"* means the [*]between ProGen and [*].

1.84. *"NDA"* means any New Drug Application as described in 21 C.F.R. § 314, or any corresponding application for Regulatory Approval in any country or jurisdiction other than the United States.

1.85. *"Net Sales"* has the meaning set forth in Exhibit D (Operating Profit or Loss Calculation).

1.86. *"Operating Profit (or Loss)"* means, for a given period of time, Net Sales of a Product in the Territory during such period *plus* Other Income for the applicable period, less the sum of: (a) Shared Manufacturing Expenses for the applicable period to support Commercialization of the Product, *plus* (b) Commercialization Costs for the Product, *plus* (c) Other Expenses, in each case ((a), (b) and (c)) incurred during such time period. For clarity, Operating Profit (or Loss) shall be determined prior to application of any income taxes, and if such terms are used individually, *"Operating Profit"* shall mean a positive Operating Profit (or Loss) and *"Operating Loss"* shall mean a negative Operating Profit (or Loss). Operating Profit (or Loss) shall be recognized and calculated in accordance with Accounting Standards.

1.87. *"Opt-Out"* has the meaning set forth in Section 11.1 (Opt-Out Right).

1.88. *"Opt-Out Date"* means the date that the Opt-Out takes effect, which shall be at least the after the required notice period set forth in Section 11.3 (Opt-Out Notice).

1.89. *"Opt-Out Notice"* has the meaning set forth in Section 11.1 (Opt-Out Right).

1.90. *"Opt-Out Party"* has the meaning set forth in Section 11.2 (Effects of Opt-Out).

1.91. *"Oral Delivery Data"* means data generated in the conduct of the Development, Manufacture or Commercialization of the Product or other Collaboration activities, that are related to the Oral Delivery Technology but not related to the Compound or the combination of the Compound with the Device.

1.92. *"Oral Delivery Technology"* means the RaniPill™ oral delivery technology Controlled by Rani that is designed for the oral delivery of biologics and drugs for therapeutic purposes, including Devices, the equipment and processes for the manufacture of Devices, information related to Transenteric delivery and the formulation of biologics and drugs for oral delivery.

1.93. *"Other Expenses"* means (a) Joint Program Damages, (b) costs related to Remedial Actions that are to be shared in accordance with Section 4.6 (Remedial Actions), (c) costs related to [*], and (d) costs or expenses to support Collaboration activities, other than Development Costs or Commercialization Costs, which the JCC shall determine should be included in Operating Profit (or Loss).

1.94. *"Other Income"* means (a) Sublicensing Revenue and (b) to the extent not already described in clause (a), other payments when recognized as income or an offset to an expense in accordance with Accounting Standards by a Party or its Affiliate that is attributable to the Product.

1.95. *"Out-of-Pocket Costs"* means amounts paid to Third Party vendors or contractors for services or materials provided by them directly in the performance of activities as contemplated herein. For clarity, Out-of-Pocket Costs do not include payments for internal items: salaries or benefits; facilities; utilities; general office or facility supplies; insurance; information technology, capital expenditures or the like unless such expenses are (i) pre-approved in writing by the Parties, (ii) agreed in writing in the Development Plan, Development Budget, Commercialization Plan, or Commercialization Budget, or (iii) agreed in writing by the JCC.

1.96. *"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.

1.97. *"Patent Rights"* means a Person's rights in and to Patents.

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

1.99. *"Peer Product"* has the meaning set forth in Section 9.4.3 (Enforcement).

1.100. *"Permitted Confidential Disclosures"* has the meaning set forth in Exhibit J.

1.101. *"Permitted Party"* means a [*] in which the relevant determination takes place (and including [*]), but excluding Excluded Parties. *"Permitted Party"* shall include any entity wholly-owned, directly or indirectly, by one or more Permitted Parties.

1.102. *"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.

1.103. *"Pharmacovigilance Agreement"* has the meaning set forth in Section 4.7 (Pharmacovigilance).

1.104. *"Phase 2 Trial"* means, with respect to the United States, any human clinical trial conducted in the specific patient population with the disease or condition of interest intended to be studied for the purposes of preliminary assessment of safety and efficacy in the indication being studied, and selection of the dose regimen(s) to be studied in a Phase 3 Clinical Trial, as described under 21 C.F.R. §312.21(b), or, with respect to a jurisdiction other than the United States, an equivalent clinical study.

1.105. *"Phase 3 Trial"* means, with respect to the United States, any human clinical trial, that, if the defined end-points are met, is intended to be a pivotal trial for obtaining Regulatory Approval in the indication being studied or to otherwise establish safety and efficacy in patients with the indication being studied for purposes of filing for Regulatory Approval with the FDA as required under 21 C.F.R. §312.21(c), or, with respect to a jurisdiction other than the United States, an equivalent clinical study

1.106. *"Platform Messaging"* has the meaning set forth in Section 4.4 (Platform Messaging).

1.107. *"PMDA"* means the Pharmaceuticals and Medical Devices Agency in Japan.

1.108. *"Post-Commercialization Report"* has the meaning set forth in Exhibit D (Operating Profit or Loss Calculation).

1.109. *"Prior Agreement"* has the meaning set forth in Section 11.5 (Prior Agreement).

1.110. *"Primary Royalty Term"* has the meaning set forth in Exhibit E (Royalties).

1.111. *"Product"* means the product comprising the Compound incorporated into the Device for oral administration.

1.112. *"Product Manufacturing Data"* means data related to the Manufacture and assembly of the Device and/or Product, but not related to the Manufacture of the Compound.

1.113. *"Product Trademark"* means any trademark rights designated by a Party or the JCC for use with the Product in the Field in the Territory.

1.114. *"ProGen"* has the meaning set forth in the preamble to this Agreement.

1.115. *"ProGen Indemnitees"* has the meaning set forth in Section 14.1 (Indemnity).

1.116. *"ProGen Program Inventions"* has the meaning set forth in Section 9.2.1 (ProGen Program Inventions).

1.117. *"Program Data"* means data generated in the performance of the Development, Manufacture or Commercialization of the Product or other Collaboration activities, including data specifically related to the combination of the Compound with the Device, but excluding Compound-Specific Data, Compound Manufacturing Data, Oral Delivery Data, and Product Manufacturing Data.

1.118. *"Program Invention"* means an invention conceived or reduced to practice during the Term in the performance of the Development, Manufacture or Commercialization of the Product or other Collaboration activities.

1.119. *"Rani"* has the meaning set forth in the preamble to this Agreement

1.120. *"Rani Indemnitees"* has the meaning set forth in Section 14.1 (Indemnity).

1.121. *"Rani Program Inventions"* has the meaning set forth in Section 9.2.2 (Rani Program Inventions).

1.122. *"Remedial Action"* means a recall, market suspension or market withdrawal of the Product or any lots thereof.

1.123. *"Recoveries"* means all cash amounts (plus the fair market value of all non-cash consideration) received by a Party from a Third Party in connection with the final judgment, award or settlement of any enforcement with respect to any Patent Rights or other intellectual property rights.

1.124. *"Regulatory Approval"* means, with respect to the 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 the Product in a country or some or all of an extra-national territory.

1.125. *"Regulatory Authority"* means any applicable Governmental Authority responsible for granting Regulatory Approvals for products, including the FDA, EMA, PMDA, and any corresponding national or regional regulatory authorities.

1.126. *"Regulatory Filing"* means, with respect to the Product, any filing with any Governmental Authority with respect to the development, manufacture, marketing, commercialization or reimbursement of such product.

1.127. *"Seller"* has the meaning set forth in Exhibit D (Operating Profit or Loss Calculation).

1.128. *"Shared Manufacturing Expenses"* means Manufacturing Expenses applicable to Compound, Device or Product Manufactured for [*] or Commercialization and all Manufacturing Expenses arising on or after Initiation of [*] of the Product (or, if sooner, the [*] for Product in a Major Market), whether for preclinical or nonclinical activities, clinical studies or Commercialization.

1.129. *"Subcontractor"* means a Third Party contractor (including contract research organizations, contract manufacturing organizations or Third Party distributors) engaged by a Party or its Affiliates on a fee-for-service basis to perform certain services or activities on behalf of and for the benefit of such Party or its Affiliates or exercise certain rights on behalf of such Party or its Affiliates, in each case, under this Agreement.

1.130. *"Sublicensee"* means a Third Party to which a Party or its Affiliate has granted or grants rights under the rights granted to such Party pursuant to this Agreement to Develop, Manufacture, or Commercialize the Product in the Field, or any further sublicensee of such rights (regardless of the number of tiers, layers or levels of sublicenses of such rights), other than any Subcontractor that is granted any such sublicense or other rights solely for the purpose of performing specific limited services or activities solely on behalf of and for the benefit of a Party or its Affiliate.

1.131. *"Sublicensing Revenue"* means any consideration (including the fair market value of non-monetary consideration such as the purchase of equity of a Party or its Affiliate) received by a Party or its Affiliate from a Sublicensee with respect to the Product for the grant of rights (including an option to obtain rights) to Develop, Manufacture, perform regulatory activities for or Commercialize the Product in the Field in the Territory.

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

1.133. *"Term"* means the period beginning on the Effective Date and ending upon the termination of this Agreement pursuant to Article 15 (Term and Termination).

1.134. *"Termination Date"* has the meaning set forth in Section 15.3.1 (General).

1.135. *"Territory"* means the entire world.

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

1.137. *"Transenteric"* means [*].

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

1.139. *"Valid Claim"* means a claim of an issued and unexpired patent, which claim has not been revoked or held invalid or unenforceable by a court or other government agency of competent jurisdiction or has not been

held or admitted to be invalid or unenforceable through re-examination or disclaimer, reissue, opposition procedure, nullity suit or otherwise.

1.140. *"VAT"* means any value added tax.

1.141. *"Voting Securities"* means securities entitled to be voted generally or in the election of directors of an entity.

2. Collaboration Scope and Governance

2.1. Conduct of the Collaboration. The Parties will collaborate to Manufacture, Develop, seek Regulatory Approvals for, and Commercialize the Product in the Field in their respective Licensed Territories, in each case in accordance with the terms and conditions of this Agreement (the *"Collaboration"*). The JCC may change the allocation of Licensed Territories at a later time based upon the Parties' relative experience, capability and readiness to Develop, seek Regulatory Approval and/or Commercialize Product in the applicable territory; however, any such change shall require the mutual agreement of the Parties.

2.2. Governance.

2.2.1. *Joint Collaboration Committee*. Promptly following the Effective Date, the Parties will establish a joint collaboration committee (the *"Joint Collaboration Committee"* or *"JCC"*) to (i) facilitate information-sharing and coordination with respect to the status and progress of Development, regulatory activities, Manufacturing and Commercialization of Product, (ii) to review and make decisions with respect to matters subject to JCC approval and (iii) provide a forum for discussing and resolving issues with respect to the conduct of the Collaboration. The Parties may designate the JCC as the forum for discussing and agreeing on matters subject to mutual agreement of the Parties hereunder. The JCC shall have no authority to amend, modify or waive compliance with this Agreement, to make decisions that conflict with the terms and conditions of this Agreement, or to create new obligations for a Party not specified in this Agreement. Each Party shall keep the other Party and the JCC informed of the progress and results of its activities under the Development Plan and Commercialization Plan and with respect to regulatory activities and supply of the Product, in each case with respect to its Licensed Territories. The JCC may establish sub-committees to coordinate or manage specific aspects of the Collaboration (e.g., product supply, financial reporting).

2.2.2. *Composition.* The JCC will be comprised of an equal number of members from each Party. The Alliance Managers appointed by each Party pursuant to Section 2.2.5 (Alliance Managers) are ex officio members of the JCC and will coordinate the scheduling and conduct of the meetings. Each Party will designate one member of such Party as its chairperson for the JCC, and the designee of each Party will serve as co-chairs of the JCC (the *"Co-Chairs"*). Either Party may replace its respective JCC members at any time upon prior written notice to the other Party. Other employees of the Parties may attend JCC meetings, but a Party will not bring a Third Party to a meeting without the other Party's prior consent.

2.2.3. *Meeting Frequency.* The JCC shall meet on a quarterly basis, or such other frequency as mutually agreed by the Parties. JCC meetings may be conducted by telephone, videoconference or in person as determined by the Parties. Either Party may request a meeting of the JCC (in person, by videoconference or teleconference) with reasonable prior written notice (it being agreed that at least [*] Business Days shall constitute reasonable notice, unless a matter is exigent) and the Parties shall reasonably cooperate to meet promptly.

2.2.4. *Decision Making.* With respect to any decisions that are subject to approval of the JCC or that the Parties agree to effect through the JCC, the JCC must have present (in person, by videoconference or telephonically) at least the chairperson of each Party (or his/her designee for such meeting). The Parties shall endeavor to make decisions where required of the JCC by consensus of the Co-Chairs. If the JCC cannot reach consensus on a matter within [*] days, then the Co-Chair of either Party may cause such dispute to be referred to the chief executive officer of each Party (or their designees)

for resolution within [*] days of being so referred. If the chief executive officers (or their designees) cannot agree on the matter within such [*] day period, then each Party shall have final decision-making authority with respect to Development and Commercialization of the Product in the Field in its Licensed Territories, subject to the other terms of this Agreement and except that (i) any Consensus Matter shall require mutual agreement of the Parties and (ii) if the Parties cannot reach consensus on an Annual Development Budget after escalation to the chief executive officers (or their designees), then the portion of the Development Budget previously approved for that Calendar Year shall apply or, if none previously approved, the prior Calendar Year's budget shall apply to the new Calendar Year.

2.2.5. *Alliance Managers*. Promptly following the Effective Date, each of the Parties will appoint a person within their organization to act as its respective alliance manager(s) for the Collaboration (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: (i) provide a single point for coordinating communication between the Parties and facilitating the cooperation of the Parties in carrying out the Collaboration, (ii) set agendas for, and take minutes at, the JCC meetings (which minutes will distributed to and agreed upon by the JCC); and (iii) identify and raise disputes to the JCC for discussion in a timely manner. A list of initial functional contacts for the Parties is set forth in Exhibit L.

2.3. Additional Compounds. During the term of the Collaboration, the Parties may discuss additional obesity compounds (including but not limited to, current or future compounds in ProGen's pipeline or discovery programs) for inclusion in the Collaboration on the same terms as set forth in this Agreement. If Rani selects any such compound(s), ProGen shall not unreasonably withhold its consent from including such compound(s) in the Collaboration on the same terms as set forth in this Agreement, provided that the compound(s) is/are otherwise unencumbered when selected and Rani is not developing at such time a compound with the same primary mechanism of action for therapeutic effect as the selected compound (e.g., [*]).

3. DEVELOPMENT

3.1. Development. Subject to the terms and conditions of this Agreement and as further set forth in the Development Plan, Rani and ProGen shall be jointly responsible for the Development of the Product in the Field in the Territory. Rani shall lead Development of the Product in the Field in the Territory for preclinical activities through Phase 1 Trials, in accordance with the Development Plan. Upon and after Initiation of the first Phase 2 Trial of the Product in the Field in the Territory, unless otherwise agreed by the JCC, each Party shall lead Development in its respective Licensed Territories in accordance with the Development Plan.

3.2. Development Plan and Budget. Development of the Product in the Field in the Territory shall be conducted in accordance with a multi-year comprehensive development plan ("*Development Plan*") and approved by the JCC and a Development Budget, which shall require approval by both Parties. An initial set of activities agreed to by the Parties is set forth in Exhibit A and shall be deemed an initial Development Plan. Following the Effective Date, the Parties shall prepare and agree upon a more comprehensive Development Plan for approval by the JCC. An initial budget for the activities on Exhibit A is set forth on Exhibit B and shall be deemed an initial Development Budget. Following the Effective Date, the Parties shall prepare and agree upon a more comprehensive Development Budget, to support the Development Plan, for approval by the Parties. The Development Plan shall stage development to focus first on developing the Product for Regulatory Approval in the Major Markets. From time to time, but at least each Calendar Year, the Parties shall update the Development Plan and Development Budget to reflect any new planned Development activities or changes in Development activities with respect to the Product. The updated Development Plan and Development Budget shall be subject to JCC review, discussion, and approval. If the terms of the Development Plan contradict, or create inconsistencies or ambiguities with, the terms of this Agreement, then the terms of this Agreement shall govern. A Party shall not conduct, directly or indirectly (through its Affiliates, Sublicensees or Subcontractors), Development of the Product in the other Party's Licensed

Territories without the prior written consent of such Party (for clarity, JCC approval of a Development Plan that specifically includes such activities shall constitute such consent).

3.3. Conduct of Program Activities. The Parties shall Develop the Product in the Field in the Territory in accordance with the Development Plan and Development Budget (subject to permitted overage as set forth herein in Section 7.1.3 (Reconciliation/Reimbursement of Development Costs)) and in compliance with all Applicable Law, including good scientific and clinical practices under the Applicable Law of the country in which such activities are conducted. Each Party shall conduct its Manufacturing and Commercialization activities hereunder in compliance with Applicable Law. A Party shall not employ or engage any Person in Joint Program Activities who has been Debarred, or, to its knowledge, is the subject of Debarment proceedings.

3.4. Records and Data-Sharing. The Parties shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of each Party in the performance of Development activities pursuant to this Agreement. Each Party shall keep the JCC regularly informed of the status of all material Development activities including regulatory activities conducted with respect to Product in the Field in the Territory pursuant to this Agreement, in such reasonable detail and frequency as the JCC shall determine. In addition, Rani shall keep the JCC regularly informed of data and progress of the Device relevant to the Product and ProGen shall keep the JCC regularly informed of data and progress of the Compound relevant to the Product, in each case including safety data and adverse event data relevant to the Product.

3.5. Development Diligence. Each Party, directly and/or with or through Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to perform the activities allocated to it in the Development Plan in order to Develop the Product and to obtain Regulatory Approval for the Product in the Field in the Major Markets within its Licensed Territories in accordance with the terms of this Agreement.

3.6. Limitations. Unless mutually agreed by the Parties in advance in writing, a Party shall not [*] nor utilize in the Development, Manufacture or Commercialization of the Product or other Collaboration activities [*] or (ii) proceed with activities with respect to the Product [*]. Notwithstanding the foregoing in this Section 3.6 (Limitations), it is not restricted or limited for [*]. Further, notwithstanding anything in this Agreement to the contrary, neither Party shall be obligated to [*] of Product, including Development, Manufacture or Commercialization of Product that contemplates or requires [*] of Product.

3.7. Costs of Development. Development Costs shall be shared by the Parties as set forth in Section 7.1 (Development Costs).

4. REGULATORY

4.1. Regulatory Responsibilities. The Parties shall collaborate in the conduct of regulatory activities in support of the Manufacture, Development and Commercialization of the Product in the Field in the Territory. Each Party shall have responsibility for regulatory strategy and activities related to Product in its respective Licensed Territories, including preparing, submitting and maintaining all Regulatory Filings and Regulatory Approvals for Product and interacting with Governmental Authorities with respect to Product, except as otherwise set forth herein or as set forth in the Development Plan.

4.2. Core Dossier. The Parties shall develop a core dossier (the *"Core Dossier"*), including manufacturing (CMC) module(s), which each Party can use to customize for country-specific Regulatory Filings for the Product in its respective Licensed Territories. The messaging in the Core Dossier shall be consistent with the Platform Messaging. The Parties shall reasonably cooperate in preparation of the Core Dossier and, as requested, country-specific Regulatory Filings for the Product, including providing information reasonably required and providing support for responding to regulatory questions related to such Party's technology (e.g., Compound with respect to ProGen and Device with respect to Rani). In lieu of providing information directly to the other Party, where applicable a Party may elect to prepare and file a drug master file (DMF) containing some or all of the information reasonably required for the other Party to reference in its Regulatory Filings for Product, and give such Party a right of reference thereto as set forth in Section 4.5.

4.3. Regulatory Filings and Communications. Each Party shall own all Regulatory Filings and Regulatory Approvals for Product in its Licensed Territories, unless otherwise agreed in writing by the JCC. Each Party shall keep the JCC informed of the status and progress of (i) the preparation of Regulatory Filings it submits, (ii) Governmental Authority review of and correspondence regarding any such Regulatory Filings, and (iii) Regulatory Approvals that it obtains with respect to the Product, in each case in the Field in the Territory. Each Party shall prepare all Regulatory Filings in the Field in its respective Licensed Territories in compliance with Applicable Law and consistent with the agreed Platform Messaging. Upon request, subject to 8.4 (Provision of Know-How), a Party shall provide promptly to the other Party copies of the Regulatory Filings it submits with respect to Product and/or regulatory correspondence received from or sent to Governmental Authorities with respect to Product in the Field in its Licensed Territories.

4.4. Platform Messaging. The Parties shall discuss in good faith and agree upon messaging to be used by each Party, its Affiliates and Sublicensees with respect to describing the Oral Delivery Technology and manufacturing of Product in Regulatory Filings, meetings and correspondence with Governmental Authorities with respect to Product and Commercialization of the Product in the Field in their respective Licensed Territories (the "*Platform Messaging*"). Upon request of either Party, the Parties shall consider in good faith any changes or additions to the Platform Messaging. The Parties agree that the Platform Messaging is intended to be accurate, consistent with data generated and compliant with all Applicable Law.

4.5. Rights of Reference. Each Party shall provide the other with all data Controlled by such Party that is reasonably necessary to support Regulatory Filings for the Product in the Field in the other Party's Licensed Territories. Each Party may file a drug master file or similar regulatory filing and grant the other a right of reference to fulfill its obligations to provide data in support of the other Party's Regulatory Filings in its Licensed Territories.

4.6. Remedial Actions**.** Each Party shall notify the other Party without undue delay (and in any event within timelines set by Applicable Law), and promptly confirm such notice in writing, if it obtains information indicating that a Product may be subject to any Remedial Action. The Parties shall assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. The Parties shall, and shall ensure that their Affiliates and Sublicensees shall, maintain adequate records to permit the Parties to trace the Manufacture, distribution and use of the Product. The JCC shall decide any matters relating to any Remedial Action with respect to any Product in the Field in the Territory, including the decision to commence such Remedial Action and the control over the conduct of such Remedial Action; *provided* however, that a Party may take immediate action with respect to its Licensed Territories under exigent circumstances or as necessary to protect patient safety. To the extent a Remedial Action is caused by a Party's failure to comply with the terms of this Agreement or gross negligence or willful misconduct of such Party (or its Affiliates or Sublicensees), such Party shall bear the costs of such Remedial Action. In all other events, the costs of the Remedial Action shall be allocated in accordance with cost-sharing under Section 7.1 (Development Costs) or Operating Profit (or Loss) sharing pursuant to Section 7.2 (Operating Profit or Loss).

4.7. Pharmacovigilance. At least [*] for the Product, the Parties shall define and finalize the actions that the Parties shall employ with respect to the Product to protect patients and promote their well-being in a mutually agreed written pharmacovigilance agreement (the *"Pharmacovigilance Agreement"*). Unless otherwise agreed by the Parties, Rani shall be the global safety database holder for the Product. The responsibilities set forth in the Pharmacovigilance Agreement shall include mutually acceptable guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports and any other information concerning the safety of the Product. Such guidelines and procedures shall be in accordance with, and enable the Parties to fulfill, local and national regulatory reporting obligations under Applicable Law. Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to require its Affiliates and Sublicensees to comply with such obligations. The Party responsible for the global safety database will maintain the global safety database pursuant to its own policy and as necessary to comply with Applicable Laws.

4.8. 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 manufacturing facilities or a review of manufacturing records with respect to Compound, Device or Product in the Field. In such event, the Parties agree to reasonably cooperate with one another 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(s). For clarity, this provision relates solely to inspections specifically related to Compound or Device to the extent such Compound or Device is used for Product, or to Product itself, and not general inspections by Governmental Authorities.

4.9. Regulatory Costs. Regulatory costs incurred in connection with the Development of the Product are included within Development Costs as set forth in Exhibit C (Development Costs) and shall be shared by the Parties as set forth in Section 7.1 (Development Costs).

5. COMMERCIALIZATION; PROFIT / LOSS SHARING

5.1. General. Each Party shall have sole responsibility for the Commercialization of Product in the Field in its Licensed Territories, subject to Consensus Matters. The Parties shall prioritize seeking Regulatory Approvals for and Commercializing the Product in the Major Markets first. Each Party shall have the right to seek Regulatory Approvals for and to Commercialize the Product, directly or indirectly through Affiliates or Sublicensees, in the Major Markets within its Licensed Territories.

5.2. Business Case. For any countries or territories outside the Major Markets that a Party desires to seek Regulatory Approval for or to Commercialize the Product, such Party shall provide to the JCC a business case therefor (*"Business Case"*), with such scope and detail as the JCC shall reasonably request. The JCC shall consider such Business Case and the commercial opportunity in such country/territory in good faith, and may take into consideration [*] and other relevant factors. If the JCC approves the Business Case (each, an *"Approved Business Case"*) for a country or territory, the JCC shall specify in the Approved Business Case the assumptions, conditions and/or criteria for pursuing such commercial opportunity. The applicable Party shall use Commercially Reasonable Efforts to Develop, seek Regulatory Approval for and Commercialize the Product in the Field in such country or territory in accordance with the Approved Business Case, and if circumstances occur such that a Party reasonably believes that such opportunity shall not meet the assumptions, conditions or criteria of the Approved Business Case, then the JCC shall reassess the commercial opportunity and determine whether to change the assumptions, conditions and/or criteria of the Approved Business Case or to withdraw approval. A Party shall seek Regulatory Approval and Commercialize the Product only in the Major Markets and such other countries/territories that the JCC approves.

5.3. Brand Strategy and Messaging. Within a reasonable time in advance of Commercialization of the Product, the Parties shall prepare and provide to the JCC for approval a brand strategy and core messaging for the Product, which shall be consistent with the Platform Messaging. The JCC shall approve the brand strategy and core messaging and each Party shall Commercialize the Product consistent with such strategy and messaging, unless otherwise agreed by the Parties.

5.4. Commercialization Plan and Reporting. On a country-by-country basis, on or before filing for the first Regulatory Approval of Product in the applicable country in its Licensed Territories, the applicable Party shall prepare and provide to the JCC a plan for the Commercialization of such Product in the Field in such country covering the period prior to commercial launch through the first full Calendar Year of Commercialization post-launch in such country, which plan shall be in such scope and detail as the JCC may reasonably request (the *"Commercialization Plan"* for such country). The Commercialization Plan shall be consistent with the Platform Messaging, brand strategy and core messaging approved by the JCC, unless otherwise agreed by the Parties. A Party shall update its Commercialization Plans at least once per Calendar Year (to cover the subsequent Calendar Year) and shall promptly provide each such update and any material amendments to each Commercialization Plan to the JCC. On a semi-annual basis (or such other frequency as determined by the JCC) commencing on the First Commercial Sale of the Product anywhere in its Licensed

Territories, a Party shall provide the JCC with a report summarizing its Commercialization activities with respect to the Product, in such scope and detail as reasonably requested by the JCC. If the terms of a Commercialization Plan contradict, or create inconsistencies or ambiguities with, the terms of this Agreement, then the terms of this Agreement shall govern.

5.5. Commercialization Budget. Commercialization of the Product in the Field in the Territory shall be conducted in accordance with a comprehensive Commercialization Budget, which the Parties shall agree upon [*] of the Product in the Territory (or such other time as mutually agreed by the Parties). From time to time, but at least each Calendar Year, the Parties shall update the Commercialization Budget to reflect any new planned Commercialization activities or changes in Commercialization activities with respect to the Product. The updated Commercialization Budget shall be subject to JCC review, discussion and approval. If the Parties (directly or through the JCC) cannot agree, even after the escalation steps in Section 2.2.4 (Decision Making), on a Commercialization Budget or certain Commercialization Costs within the Commercialization Budget, then for any proposed Commercialization Costs which have not been agreed upon, a Party may incur (at its own risk and cost) such Commercialization Costs to Commercialize the Product in the Field in its applicable Licensed Territories and such costs shall [*].

5.6. Commercialization Diligence**.** Each Party, directly and/or with or through Affiliates or Sublicensees, shall use Commercially Reasonable Efforts to perform the activities allocated to it in the Commercialization Plan and/or by the JCC in order to Commercialize the Product in the Field in its respective Licensed Territories.

5.7. Commercialization Costs. Commercialization Costs shall be addressed as set forth in Section 7.2 (Operating Profit (or Loss)).

6. MANUFACTURE AND SUPPLY

6.1. Manufacturing Responsibilities. The JCC shall approve a supply plan for the Product to support the Collaboration. Unless otherwise determined by the JCC, ProGen shall be solely responsible for Manufacturing and supplying Compound for all Development and Commercialization of the Product in the Territory, including for all preclinical activities as set forth in the Development Plan, and Rani shall be solely responsible for Manufacturing and supplying the Product (the Device, and incorporating the Compound into the Device) for all Development and Commercialization of the Product in the Territory, including for all preclinical activities as set forth in the Development Plan. Within a reasonable time after the Effective Date, the Parties shall execute one or more supply agreements and quality agreements to govern (i) the Manufacturing and supply to Rani of Compound by ProGen (or its CMO) and (ii) the Manufacturing and supply to ProGen of Product by Rani (or its CMO).

6.2. Manufacturing Transfer. The JCC may agree in the supply plan on the timing/stage at which each Party shall transfer Manufacturing of Compound (by ProGen) and Product (including Device) (by Rani), respectively, to one or more mutually agreeable CMOs, at the transferring Party's cost (not subject to cost-sharing hereunder). The JCC shall take into consideration the stage of development of the Product, forecast of supply and demand requirements, capital investment required, intellectual property protection, cost and other relevant factors. A Party shall not be obligated to undertake a transfer of its Manufacturing of Compound or Product, as the case may be, to a CMO provided [*]. After [*], then the Parties shall discuss in good faith whether a transfer of Manufacturing to a CMO (or different CMO) would be in the best interest of the Collaboration, and a Party shall not unreasonably withhold, condition or delay its consent for a transfer of its Manufacturing of Compound or Product (including Device), as the case may be, to support the Collaboration. If it is agreed to transfer Manufacturing of the Compound or Product, then as applicable (i) ProGen shall use Commercially Reasonable Efforts to transfer the Manufacturing of Compound to a mutually agreeable CMO, at its own cost, for the Manufacture and supply of Compound for Development and Commercialization of the Product; or (ii) Rani shall use Commercially Reasonable Efforts to transfer the Manufacturing of Product (Compound incorporated into the Device) to a mutually agreeable CMO, at its own cost, for the Manufacture and supply of Product for Development and Commercialization of the Product. Notwithstanding the foregoing, a Party may elect at any time to use a CMO to support its Manufacturing and supply obligations (i.e., ProGen with respect to Manufacturing Compound and Rani with respect to Manufacturing Product);

provided it shall not use an Excluded Party (other than [*]) therefor without the other Party's prior written consent. In addition, notwithstanding the foregoing in this Section 6.2 (Manufacturing Transfer), [*], then Rani shall have a right by written notice to require ProGen to [*] to enable supply of Compound from such CMO for [*] and/or Commercialization of Product, in which event ProGen shall execute a transfer of Manufacturing of Compound as set forth above in this Section 6.2 (Manufacturing Transfer) except that the cost of the transfer shall be shared by the Parties as Operating Profit (or Loss). Following completion of a transfer of Manufacturing by a Party, the other Party may request to engage with the applicable CMO to obtain supply directly from such CMO and the transferring Party shall not unreasonably withhold, condition or delay its consent therefor; in which case, the license granted under Section 8.1 (License to ProGen) or Section 8.2 (License to Rani), as the case may be, to the Party receiving supply from such CMO shall include the right to "have made" Compound or Product by such CMO in accordance with this Agreement.

6.3. Manufacturing Costs. ProGen shall bear all Manufacturing Expenses for the Compound, at its own cost, and Rani shall bear all Manufacturing Expenses for the Product (including the Device, but excluding the cost of Compound supply, which will be borne by ProGen), at its own cost. Notwithstanding the foregoing, the Parties shall share the costs of Shared Manufacturing Expenses to support Development and Commercialization of the Product as set forth in Section 7.1 (Development Costs) and Section 7.2 (Operating Profit (or Loss). Each Party may conduct its Manufacturing and supply activities for Development and Commercialization directly itself or through a Third Party CMO. Unless otherwise agreed by the Parties, each Party shall bear its own costs related to a transfer of Manufacturing to a CMO.

6.4. Specifications. Rani shall Manufacture Product in accordance with regulatory requirements and Applicable Law. ProGen shall Manufacture Compound in accordance with regulatory requirements and Applicable Law. The supply agreements and/or supply plan shall set forth the dosage forms and specifications for supply of Compound and Product. Unless otherwise mutually agreed by the Parties, ProGen agrees to Manufacture and supply Compound in at least the dosage forms set forth in Exhibit G.

7. FINANCIAL

7.1. Development Costs.

7.1.1. *Cost Sharing***.** Development Costs for Product incurred during the Term by the Parties shall be borne 50% by Rani and 50% by ProGen. For the avoidance of double-counting, the Parties acknowledge and agree that Commercialization Costs shall not include Development Costs for purposes of calculating Operating Profit (or Loss) in accordance with Section 7.2 (Operating Profit or Loss) and, likewise, that any amounts included in Commercialization Costs shall not be included in Development Costs.

7.1.2. *Development Cost Reporting.* Development Costs shall initially be borne by the Party incurring the cost or expense, but shall be subject to reconciliation payments as provided in Section 7.1.3 (Reconciliation/Reimbursement of Development Costs). Each Party shall maintain records of Development Costs incurred by it and its Affiliates with respect to Development of the Product. The procedures for quarterly reporting of actual results, quarterly review and discussion of potential discrepancies, quarterly reconciliation, reasonable cost forecasting, and other finance and accounting matters related to Development Costs shall be determined by the JCC (the "*Development Reconciliation Procedures*"). Such procedures shall provide the ability for each Party to comply with its respective financial reporting requirements. Each Party shall calculate Development Costs of the Product in accordance with the Development Reconciliation Procedures. The Development Reconciliation Procedures shall provide that within [*] Business Days after the end of each Calendar Quarter, each Party shall submit to the JCC a report, in such reasonable detail and format as is established by the JCC of all Development Costs incurred by such Party during such Calendar Quarter with respect to Product in the Field. Within [*] Business Days following the receipt of such report, each Party shall have the right to request reasonable additional information related to the other party's and its Affiliates' Development Costs during such Calendar Quarter with respect to Product in order to confirm that such other Party's spending conforms with the Development

Budget. The JCC shall establish reasonable procedures for the Parties to share estimated Development Costs for each Calendar Quarter with respect to Product prior to the end of such Calendar Quarter, to enable each Party to appropriately accrue its share of Development Costs for financial reporting purposes. The JCC may establish a financial subcommittee to handle its responsibilities under this Section 7.1.2 (Development Cost Reporting).

7.1.3. *Reconciliation/Reimbursement of Development Costs.* Unless otherwise agreed by the JCC, the Parties shall reconcile cost-sharing of Development Costs for Product as set forth in this Section 7.1.3 (Reconciliation/Reimbursement of Development Costs).

7.1.3.1. On a Calendar Quarter basis, the Party (with its Affiliates) that incurs more than its fifty percent (50%) share of the total actual Development Costs for the Product shall be paid by the other Party an amount of cash sufficient to reconcile each Party bearing an equal amount of actual Development Costs for Product in such Calendar Quarter. Notwithstanding the foregoing, on a Calendar Year-to-date basis, the Parties shall not share any Development Costs in excess of the amounts allocated for such Calendar Year-to-date period in the Annual Development Budget for such Calendar Year; provided, however, that Development Costs for Product in excess of the Annual Development Budget shall be included in the calculation of Development Costs to be shared by the Parties if (i) the JCC approves such excess Development Costs (either before or after they are incurred), which approval shall not be unreasonably withheld to the extent the Development Costs for Product in excess of the Development Budget were not within the reasonable control of the Party (or Affiliate) incurring such expense or (ii) to the extent such excess Development Costs for Product do not exceed by more than [*] the total Development Costs allocated to be incurred by such Party and its Affiliates in the applicable Calendar Year-to-date period in accordance with the Annual Development Budget for such Calendar Year. If any excess Development Costs for Product are excluded from sharing by the Parties for a particular Calendar Year-to-date period pursuant to the foregoing sentence, such excess Development Costs shall be carried forward to the subsequent Calendar Quarters (provided that such Calendar Quarters fall within the same Calendar Year) and, to the extent the total Development Costs for Product incurred by such Party and its Affiliates for the Calendar Year-to-date as of the end of such subsequent Calendar Quarter are less than [*] of the aggregate Development Costs allocated to such Party under the Annual Development Budget for such Calendar Year-to-date period, such carried forward amounts shall be included in Development Costs to be shared by the Parties for such Calendar Year-to-date-period (i.e., so that the total Development Costs incurred by such Party and its Affiliates that are shared pursuant to this Section 7.1 (Development Costs) during any Calendar Year do not exceed [*] of the Development Costs allocated to such Party under the Annual Development Budget for such Calendar Year, unless otherwise approved by the JCC).

7.1.3.2. The Development Reconciliation Procedures shall provide for the JCC to develop each Calendar Quarter a written report setting forth in reasonable detail the calculation of any net amount owed by one Party to the other, as necessary to accomplish the sharing of Development Costs as well as any reconciliation payment that is due from one Party to the other with respect to such Calendar Quarter, and to prepare such reports promptly following delivery of the report described in Section 7.1.2 (Development Cost Reporting) such that the written report is finalized within [*] days after the end of the Calendar Quarter. The net amount payable to accomplish the sharing of Development Costs as provided under this Agreement shall be paid by Rani or ProGen, as the case may be, within [*] days after finalizing the written report; *provided*, *however*, that in the event of any disagreement with respect to the calculation of such payment, any undisputed portion of such payment shall be paid in accordance with the foregoing timetable and the remaining, disputed portion shall be paid within [*] Business Days after the date on which the Parties, using good faith efforts, resolve the dispute.

7.1.3.3. Upon request, each Party shall consider in good faith other reasonable procedures proposed by the other Party for sharing financial information in order to permit each Party to close its books periodically in a timely manner.

7.2. Operating Profit or Loss. The Parties shall share the Operating Profit (or Loss) for the Product in the Territory as follows: Rani shall bear (and be entitled to) 50%, and ProGen shall bear (and be entitled to) 50%. The JCC shall establish reasonable procedures to enable each Party to comply with its financial reporting requirements related to its share of Operating Profit (or Loss). The procedure for calculating Operating Profit (or Loss) for the Product is set forth in Exhibit D (Operating Profit or Loss Calculation). To the extent any matter relating to calculating Operating Profit (or Loss) for Product is not explicitly addressed in Exhibit D, it shall be determined by the JCC.

7.3. Financial Subcommittee. Upon the request of either Party, the JCC shall establish a subcommittee to carry out the JCC's responsibilities and to coordinate the activities and reporting by the Parties as set forth in Section 7.1 (Development Costs) and 7.2 (Operating Profit or Loss) and to assist the JCC in its responsibilities with respect to the review and resolution of financial matters. In particular, the subcommittee shall:

7.3.1. facilitate the creation of each Development Budget (and Annual Development Budget);

7.3.2. reconcile financial and accounting matters between the Parties;

7.3.3. initiate and execute an effective and efficient revenue and cost-sharing process (cross-charges);

7.3.4. review and recommend for the Parties' consideration of modifications to the FTE Rate used to calculate shared costs;

7.3.5. discuss, prepare and determine whether to approve for submission to the JCC for approval a FTE time tracking approach to be followed by each Party;

7.3.6. cooperate to ensure that the Development Budget can be interpreted for the purposes of both Parties' internal financial and audit reporting requirements, including each Party's fiscal year reporting; and

7.3.7. implement a series of reporting requirements for actual and forecasted financial information, available at times to be agreed by the Parties through the subcommittee, consistent with the need to report the results of cost-sharing and/or sharing of Operating Profit (or Loss).

7.4. Payment Method. All payments made hereunder between the Parties shall be made in U.S. Dollars. Each Party shall pay all sums due hereunder by wire transfer or electronic funds transfer (EFT) in immediately available funds. Each Party shall promptly notify the other Party of the appropriate account information to facilitate any such payments. All amounts payable under this Agreement shall be paid in full (subject to Section 7.8 (Withholding) and Section 7.9 (VAT))

7.5. Currency Conversion. If currency conversion shall be required in connection with any payment hereunder, such amount shall be converted into the U.S. Dollar equivalent using such Party's standard conversion method consistent with Accounting Standards in a manner consistent with such Party's customary and usual conversion procedures used in preparing its financial statements applied on a consistent basis, *provided* that such procedures use a widely accepted source of published exchange such as published by OANDA.com or *Bloomberg Professional*, a service of Bloomberg L.P. (otherwise the rate established by such a widely accepted source shall be used).

7.6. Audits. Each Party shall (and shall ensure that its Affiliates and Sublicensees shall) keep complete and accurate records in sufficient detail to permit the other Party to confirm the accuracy of costs and expenses reported and payments due hereunder. Such records of a Party shall 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 Calendar Year to which they pertain. Each Party shall 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. 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 shall only be subject to [*]. Should the inspection lead to the discovery of a discrepancy, then the appropriate Party shall pay to the other Party the amount of the discrepancy. The auditing Party shall 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 shall 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 shall be subject to the withholding and remittance provisions of Section 7.8 (Withholding).

7.8. Withholding. In the event that Applicable Law requires a Party to pay or withhold Taxes with respect to any payment to be made by such Party pursuant to this Agreement, then the paying Party shall notify the receiving Party in writing of such payment or withholding requirements prior to making the payment to such Party and provide such assistance to the receiving Party, including the provision of such documentation as may be required by a tax authority, as may be reasonably necessary in the receiving Party's efforts to claim an exemption from or reduction of such Taxes. The paying Party shall, in accordance with Applicable Law, withhold Taxes from the amount due, remit such Taxes to the appropriate tax authority, and furnish the receiving Party with proof of payment of such Taxes within [*] Business Days following obtaining the relevant payment certificate. If Taxes are paid to a tax authority, the paying Party shall provide such assistance to the receiving Party as is reasonably required to obtain a refund of Taxes withheld, or obtain a credit with respect to Taxes paid.

7.9. VAT. All payments due from one Party to the other pursuant to this Agreement shall be paid exclusive of any VAT (which, if applicable, shall be payable by the paying Party upon receipt of a valid VAT invoice).

7.10. Late Payment. Any payments or portions thereof due hereunder which are not paid when due shall bear interest at the Contract Interest Rate calculated on the number of days such payment is delinquent. This Section 7.10 (Late Payment) shall in no way limit any other remedies available to either Party.

7.11. No Self-Dealing. A Party shall not use a Subcontractor or Sublicensee for activities that are subject to cost-sharing hereunder if the management, or one or more principals or significant shareholders of such Party (or its Affiliate) have a material economic interest in the Subcontractor or Sublicensee, without the other Party's prior written consent. All contracts with Subcontractors and/or Sublicensees shall be on arms'-length terms.

8. Grant of License

8.1. License to ProGen. Effective as of the Effective Date and subject to the terms and conditions of this Agreement, Rani hereby grants to ProGen during the Term an exclusive right and license (except as to Rani and its Affiliates and Sublicensees) under the Licensed Rani Patents and Licensed Rani Know-How solely to Develop the Product in the Field in the Territory in accordance with the Development Plan and an exclusive right and license (even as to Rani and its Affiliates, except as set forth in Section 8.6 (Retained Rights)) to seek Regulatory Approval for and to use, sell, offer for sale, import and commercialize the Product in the Field in ProGen's Licensed Territories, in each case in accordance with this Agreement. Such licenses shall include the right to sublicense only as set forth in Section 8.3 (Sublicensing). The licenses under this Section do not include a right to make or have made the Device or Product. The licenses under this Section shall only include rights to have Product made by a CMO following a transfer of Manufacturing of Product by Rani to such CMO, as set forth in Section 6.2 (Manufacturing Transfer). ProGen shall not Develop or Commercialize the Product outside the Field in the Territory without the prior written consent of Rani.

8.2. License to Rani. Effective as of the Effective Date and subject to the terms and conditions of this Agreement, ProGen hereby grants to Rani during the Term an exclusive right and license (except as to ProGen and its Affiliates and Sublicensees) under the Licensed ProGen Patents and Licensed ProGen Know-How solely to Develop the Product in the Field in the Territory in accordance with the Development Plan and an exclusive right and license (even as to ProGen and its Affiliates, except as set forth in Section 8.6 (Retained Rights)) to seek Regulatory Approval for and to use, sell, offer for sale, import and commercialize the Product in the Field in Rani's Licensed Territories, in each case in accordance with this Agreement. Such licenses shall include the right to sublicense only as set forth in Section 8.3 (Sublicensing). The licenses under this Section

do not include a right to make or have made the Compound. The licenses under this Section shall only include rights to have Compound made by a CMO following a transfer of Manufacturing by ProGen to such CMO, as set forth in Section 6.2 (Manufacturing Transfer). Rani shall not Develop or Commercialize the Product outside the Field in the Territory without the prior written consent of ProGen.

8.3. Sublicensing. A Party shall not have the right to sublicense the rights and licenses granted to it under Section 8.1 (License to ProGen) or Section 8.2 (License to Rani), as applicable, without the applicable Licensor's consent. Notwithstanding the foregoing, each Party, without the Licensor's consent, (a) may sublicense the rights and licenses granted to it under Section 8.1 (License to ProGen) or Section 8.2 (License to Rani), as applicable, to its Affiliates, *provided* that such Party remains primarily responsible for the activities of any such Affiliates, (b) may use customary Subcontractors in the performance of activities allocated to it hereunder, *provided* that such Party remains primarily responsible for the activities of any such Subcontractors, and (c) shall have the right to sublicense the rights and licenses granted to it under Section 8.1 (License to ProGen) or Section 8.2 (License to Rani), as applicable, with respect to one or more of its Licensed Territories to one or more Sublicensees, *provided* that such Sublicensees are Permitted Parties. All revenue from licensing/sublicensing Product rights in Licensed Territories shall be shared equally by the Parties in accordance with Section 7.2 (Operating Profit or Loss). Notwithstanding any sublicensing under this Section 8.3 (Sublicensing), the Licensee shall remain responsible hereunder for the full and complete performance of all of Licensee's obligations and duties under this Agreement and compliance of any such Third Party and sublicense with the terms of this Agreement. The Party granting any Third Party sublicense hereunder shall provide the other Party with [*] other than [*]. To the extent reasonably necessary, such Party may [*]. Any such sublicense agreement shall obligate such sublicensee to comply with all relevant restrictions, limitations, and obligations in this Agreement. Any use of a Third Party (including Subcontractors) to perform obligations under this Agreement shall be pursuant to a written agreement that is consistent with the terms of this Agreement, including that the Third Party undertakes in writing commercially reasonable obligations of confidentiality and non-use regarding Confidential Information that are substantially the same as those undertaken by the Parties with respect to Confidential Information under this Agreement, and terms that are materially as protective of the other Party and its intellectual property and proprietary rights as the terms of this Agreement. Upon the request of either Party, prior the sharing of any Compound, Devices or Product with Third Parties, the Parties shall agree discuss and agree in good faith upon procedures therefor, in order to protect the confidentiality and intellectual property of the other Party (i.e., each Party's Background IP, ProGen Program Inventions, or Rani Program Inventions), including limitations on granting to Third Parties access to and use of Compound, Device or Product prior to commercial launch of the Product.

8.4. Provision of Know-How. Following the Effective Date, the Parties shall cooperate in the sharing of Information relating to Product to the extent reasonably required to support their respective responsibilities under this Agreement, including the Development Plan, Manufacturing, Commercialization, and regulatory activities; *provided* that a Party shall not be obligated to disclose any Information that is (i) proprietary or trade secret with respect to such Party and (ii) not reasonably necessary for the other Party to perform its responsibilities or exercise its rights hereunder. Unless otherwise agreed by the Parties, Information shared under this Section 8.4 (Provision of Know-How) shall be disclosed in the English language.

8.5. Trademarks.

8.5.1. *Product Brand Name*. Prior to Commercialization of the Product, the JCC shall decide upon one or more brand name(s) or trademark(s) for the Product and the Parties shall utilize such brand name(s) or trademark(s) for the Commercialization of the Product in the Field in their respective Licensed Territories. The JCC shall determine the timing for selecting brand name(s) or trademark(s) and the Parties shall use a customary process to identify and clear the use of any such brand name(s) (e.g., utilize a recognized, Third Party firm therefor). If the JCC cannot agree on one or more brand name(s) or trademark(s) for the Product, then each Party may determine the brand name(s) and/or trademark(s) for its own Licensed Territories. The costs of selecting and clearing use of brand

name(s) and/or trademark(s) for Product shall be included within Operating Profit (or Loss) as set forth in Section 7.2 (Operating Profit or Loss).

8.5.2. *Company Trademarks*. If a Party is reasonably required due to regulatory requirements or Applicable Law to include the other Party's trademark on any labeling, packaging, or other materials in connection with the Product, then the Parties shall reasonably cooperate to grant each other an appropriate license to use such trademark for such purposes. Upon request of the licensor, the Parties will enter into a written agreement for such license, which will include customary trademark quality standards.

8.6. Retained Rights. No rights to either Party's Patent Rights, Information, trademarks, or other proprietary rights are granted pursuant to this Agreement except as expressly set forth herein, and all other rights are reserved. Notwithstanding the licenses granted in this Article 8 (Grant of License), each Party retains rights to perform (itself or through its Affiliates or Subcontractors or licensees) its obligations and exercise its rights under this Agreement, including any obligations to manufacture and/or supply Compound or Product.

8.7. Exclusivity. Other than with respect to Product and activities under this Agreement, each Party agrees that it shall not, itself or through its Affiliates, [*] of any product constituting [*] that is intended to bind as its primary mechanism of action for therapeutic effect [*] ("*Exclusive Activities*"). After the date of [*] for Product, a Party shall [*]. For clarity, the obligations in this Section 8.7 (Exclusivity) shall not apply to [*] intended to bind [*] in each case as its primary mechanism of action for therapeutic effect.

8.8. Acquiror IP. If a Party undergoes a Change of Control, the Information and Patent Rights of the acquiring Person and its affiliates prior to the Change of Control shall not be included in the licenses granted by the Parties in Section 8.1 (License to ProGen) or Section 8.2 (License to Rani).

8.9. Cooperation Generally. The Parties shall 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 Commercialization of the Product.

9. Intellectual Property

9.1. Background IP. Each Party shall own and retain all rights, ownership, and interests in and to its Background IP, subject to any applicable licenses set forth in this Agreement.

9.2. Program Inventions.

9.2.1. *ProGen Program Inventions*. ProGen shall own Program Inventions solely related and limited to Compound [*] (*"ProGen Program Inventions"*).

9.2.2. *Rani Program Inventions*. Rani shall own Program Inventions that are related to its Oral Delivery Technology [*] (*"Rani Program Inventions"*).

9.2.3. [*]

9.2.4. *Joint Program Inventions*. All Program Inventions that are solely related to the combination of the Device with Compound [*] (collectively, *"Joint Program Inventions"*) shall be jointly owned by the Parties.

9.2.5. *Cooperation*. Each Party shall reasonably and promptly cooperate with the other to effectuate assignment of Program Inventions consistent with the rights set forth in this Section 9.2 (Program Inventions). A Program Invention shall be Confidential Information of the Party who owns the Program Invention.

9.3. Data.

9.3.1. *Party Data*. ProGen shall solely own Compound-Specific Data and Compound Manufacturing Data, and Rani shall solely own Oral Delivery Data and Product Manufacturing Data; in each case, subject to the applicable licenses set forth in this Agreement.

9.3.2. *Program Data*. The Parties shall jointly own Program Data, with equal undivided right to use and exploit Program Data without consent from or accounting to the other Party, but in all cases subject to the confidentiality and publication provisions and other obligations, licenses and limitations set forth in this Agreement.

9.4. Patent and IP Handling.

9.4.1. *Notice*. Each Party shall promptly notify the other upon becoming aware of (i) any suspected or threatened material infringement of any Licensed IP with respect to Product or a Peer Product, (ii) any claim that such Party's, or its Affiliates' or Sublicensees' exercise of the rights granted hereunder infringes any rights or Patent Rights of a Third Party, (iii) any claims of alleged infringement of Third Party Patent Rights with respect to the manufacture, use, sale, offer for sale, importation or exploitation of the Product hereunder, (iv) any suspected or actual material misappropriation of Licensed Rani Know-How or Licensed ProGen Know-How regarding the Product, and/or (v) any suspected or actual material infringement or dilution of the Product Trademark(s), all of the foregoing, (i) through (v), anywhere in the world.

9.4.2. *IP Matters*. Except as otherwise expressly set forth in this Agreement, each Party, at its sole cost, shall have the sole right, but not the obligation, to (i) 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, (ii) subject to Section 9.4.3 (Enforcement) enforce its Patent Rights and other intellectual property rights against any actual, alleged or threatened infringement or misappropriation by Third Parties, and (iii) settle any such matters in its sole discretion, subject to its obligations, and the licenses and rights granted, under this Agreement.

9.4.3. *Enforcement*. Each Party shall have the sole right to enforce its Patent Rights against Third Parties. Notwithstanding the foregoing, if a Licensee desires to enforce the Licensor's Licensed IP against a Third Party with respect to a Third Party product comprising [*] (a *"Peer Product"*) in its Licensed Territories, it will raise such matter with the Licensor and the Parties shall discuss such matter in good faith. If Licensor determines in its sole discretion to enforce its Licensed IP against a Third Party with respect to a Peer Product, Licensor may, in its sole discretion, choose to do so itself or to allow Licensee to do so. If Licensor allows Licensee to directly enforce Licensor's Licensed IP with respect to a Peer Product, then Licensee shall handle enforcement itself or through outside counsel reasonably acceptable to Licensor and directed by Licensee. In the event Licensee is allowed to enforce Licensor's Licensed IP under this Section 9.4.3 (Enforcement), the Parties shall reasonably cooperate in such action, Licensor shall have a right to participate in such enforcement, and Licensee shall seek and reasonably consider Licensor's comments before determining the strategy. Without limiting the foregoing, Licensee shall keep Licensor advised of all material communications, actual and prospective filings, or submissions regarding such action, and shall provide Licensor copies of and an opportunity to review and comment on any such material communications, filings, and submissions. Licensee shall not settle, compromise or consent to any judgment in, any action under this Section 9.4.3 (Enforcement), without Licensor's prior written consent (which shall be in its sole discretion). If at any time during an enforcement action handled by Licensee the defending Third Party asserts that the Licensor's Licensed IP is invalid or unenforceable, Licensor shall have a right to assume control and direction of the enforcement action from Licensee.

9.4.4. *Joint Patent Rights*. Notwithstanding the foregoing in Section 9.4.2 (IP Matters) and Section 9.4.3 (Enforcement), this Section 9.4.4 (Joint Patent Rights) shall apply to Joint Patent Rights. The Parties shall agree upon procedures for the filing, prosecution, maintenance, defense, and enforcement of Joint Patent Rights. Unless otherwise agreed by the Parties, the Parties shall select a mutually agreeable outside counsel to manage the preparation, filing (including filing for correction of claims or specifications), prosecution, maintenance, and defense of Joint Patent Rights, as well as preparation and filing for any patent term extensions or similar protections therefor. Unless otherwise mutually agreed, the Parties shall direct such outside counsel to (a) file, prosecute,

maintain and defend such Joint Patent Rights for the benefit of both Parties and taking both Parties' interests into account, (b) provide each Party with copies of and an opportunity to review and comment upon the text of the applications relating to the Joint Patent Rights as soon as practicable (but in no event less than [*] days) before filing, (c) provide each Party with a copy of each submission made to and document received from a patent authority, court or other tribunal regarding Joint Patent Rights reasonably promptly after making such filing or receiving such document, together with notice of its filing date and application number, (d) keep each Party advised of the status of all material communications, actual and prospective filings or submissions regarding the Joint Patent Rights, and giving each Party copies of and an opportunity to review and comment on any such material communications, filings and submissions proposed to be sent to any patent authority or judicial body, and (e) reasonably consider in good faith each Party's comments on the communications, filings and submissions for the Joint Patent Rights. Costs of filing, prosecution, maintenance and defense of Joint Patent Rights, and Recoveries from enforcement of Joint Patent Rights, shall be shared equally by the Parties; except that either Party may elect at any time to forfeit its rights in a Joint Patent Right (on a patent-by-patent and country-by-country / territory-by-territory basis) by giving [*] days written notice to the other Party, in which case the forfeiting Party (x) forfeits to the other Party its rights in and to the applicable Joint Patent Right in the applicable territory such that the other Party shall have sole right, title and interest therein in such territory (and it shall no longer be a Joint Patent Right in such territory), and (y) shall not have any obligation to share costs incurred (and shall not have a right to receive Recoveries received from enforcement activities ongoing or occurring) with respect to such forfeited Joint Patent Right in the applicable territory after such [*] day notice period. If the non-forfeiting Party elects, by written notice to the forfeiting Party, also to forfeit its rights in and to the same Joint Patent Right in the applicable territory within the [*] day notice period of the forfeiting Party, then both Parties shall cooperate to wind-down any prosecution, maintenance or other activities with respect to such Joint Patent Right in the applicable territory and shall [*]. If either Party desires to enforce a Joint Patent Rights against a Third Party, it shall notify the other Party and [*].

9.5. Defense and Settlement of Product Infringement Claims. Each Party shall have the sole right to defend itself against any claims that any Patent Right or other right owned by a Third Party is infringed by the manufacture, use, sale, offer for sale, importation or other exploitation of the Product (each, a *"Product Infringement Claim"*) by such Party. The Parties shall notify each other of any Product Infringement Claims and reasonably cooperate with one another in the defense and any settlement of such claims, including potentially adding the other Party to the action if it is better positioned to defend such claim. Neither Party or its Affiliates or Sublicensees with settle, compromise, or consent to any judgment of any Product Infringement Claim without the prior written consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed. With respect to Product Infringement Claims that relate to activities within the Collaboration (ie., prior to an Opt-Out), costs associated with the defense, damages and settlement of Product Infringement Claims shall be [*] except to the extent the Product Infringement Claim or costs related thereto are [*]. Any settlement of the Product Infringement Claim shall require [*].

9.6. Third Party IP. Neither Party will have an obligation to perform an activity hereunder if such activity would infringe (or contribute to infringement of) the intellectual property rights of a Third Party unless and until the appropriate Party(ies) obtain a license, modify the potentially infringing activity (without materially affecting the performance of the Joint Program Activities), or otherwise resolve such potential infringement, which the Parties shall use good faith, reasonable efforts to do. The JCC may facilitate discussion between the Parties regarding any potential license to Third Party intellectual property rights that a Party considers obtaining with respect to Product.

9.7. Cooperation. Each Party agrees to reasonably cooperate (and to cause any employee or Affiliate, Sublicensee or contractor who worked on the Development, Manufacture, or Commercialization of the Product or other Collaboration activities to cooperate) in the preparation, filing, prosecution, maintenance, enforcement and defense of any Program Inventions and intellectual property rights related thereto, and in the enforcement or defense of Patent Rights or other intellectual property rights to the extent related to the Product. Such

cooperation includes: (i) executing all papers and instruments, or requiring such Persons to execute such papers and instruments, so as to effectuate the ownership of Program Inventions or other intellectual property as set forth in Section 9.2 (Program Inventions) or the remainder of Article 9 (Intellectual Property), and to enable the owning Party to apply for and to prosecute patent applications in any country; and (ii) promptly informing the other Party of any matters coming to its attention that may affect the preparation, filing, prosecution, enforcement or defense of any such patent application.

9.8. Allocation of Recoveries. Except as set forth below in this Section 9.8 (Allocation of Recoveries), each Party shall retain any and all Recoveries from actions related to their Background IP or intellectual property assigned to such Party. Prior to an Opt-Out Date, all Recoveries from actions brought under Section 9.4.3 (Enforcement) with respect to a Peer Product shall first go to reimburse the Parties for any costs incurred with respect to such enforcement action, and the remainder shall be included in the Operating Profit (or Loss) calculation under Section 7.2 (Operating Profit (or Loss)). After an Opt-Out Date, each Party shall have the right to retain [*] of any Recoveries from actions related to its intellectual property related to activities occurring after the Opt-Out Date. After any termination of this Agreement, each Party shall have the right to retain [*] of any Recoveries from actions related to its intellectual property, even if the infringing activity occurred during the Term of the Agreement.

9.9. Employee Agreements. Prior to beginning work relating to any aspect of the subject matter of this Agreement (including being given access to the other Party's Licensed IP or Confidential Information of the other Party in relation to such work), each employee, consultant or agent of a Party shall have either (i) signed or shall be bound to a written non-disclosure and invention assignment agreement pursuant to which each such person agrees to comply with all of the obligations of the Party, substantially including: (a) promptly reporting any Program Invention, as appropriate; (b) assigning to Rani or ProGen, as applicable, all of his or her right, title and interest in and to any such Program Invention; (c) cooperating in the preparation, filing, prosecution, maintenance, enforcement and defense of any intellectual property rights covering or claiming such Program Inventions; (d) performing all acts and signing, executing, acknowledging and delivering any and all papers, documents and instruments required for effecting the assignment of or for evidencing ownership in such Program Inventions; and (e) abiding by the obligations of confidentiality and non-use set forth in this Agreement or (ii) be bound by Applicable Law to assign to Rani or ProGen, as appropriate, all of his or her right, title and interest in and to any such Program Invention. It is understood and agreed that any such non-disclosure and invention assignment agreement need not be specific to this Agreement, and that the operation of a collective employment policy sufficient to achieve the intent of the foregoing shall be sufficient to satisfy such obligation. Each Party shall be responsible for any compensation and any other payments due to its own inventors of any Patent Right.

9.10. Patent Challenge. A Party shall provide written notice to the other Party at least [*] days in advance if such Party, or its Affiliate or Sublicensee intends to initiate or participate directly or indirectly in a legal proceeding (whether in a court, before a patent authority or otherwise) to challenge the patentability, validity, ownership, enforceability, term or scope of the other Party's Patent Rights within its Licensed IP (a *"Patent Challenge"*). If a Party, its Affiliate or Sublicensee participates directly or indirectly in a Patent Challenge, the non-participating Party may notify the participating Party that [*].

10. Confidentiality and Publications

10.1. Confidentiality; Exceptions. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the Term and for [*] thereafter, the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any confidential and proprietary information and materials furnished to it by the other Party pursuant to this Agreement (collectively, *"Confidential Information"*). For clarity, Confidential Information of a Party shall include all information and materials disclosed by such Party or its designee that (i) is marked as "Confidential," "Proprietary" or with similar designation at the time of disclosure or (ii) by its nature can reasonably be expected to be considered Confidential Information by the recipient. Information disclosed orally shall not be required to be identified as confidential information to be considered Confidential

Information. Notwithstanding the foregoing, Confidential Information shall not include any information to the extent that it can be established by written documentation by the receiving Party that such information:

10.1.1. was already known to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), at the time of disclosure;

10.1.2. was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

10.1.3. became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

10.1.4. was independently developed by the receiving Party (without reference to or use of Confidential Information of the other Party) as demonstrated by documented evidence; or

10.1.5. was disclosed to the receiving Party, other than under an obligation of confidentiality (except to the extent such obligation has expired or an exception is applicable under the relevant agreement pursuant to which such obligation was established), by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.

10.2. Authorized Disclosure. Except as expressly provided otherwise in this Agreement, each Party may disclose Confidential Information of the other Party solely as follows: (i) under appropriate confidentiality provisions substantially equivalent to those in this Agreement to the extent such disclosure is reasonably necessary or useful in performing its obligations under this Agreement or in conducting Development, Manufacturing, regulatory activities or Commercialization of Product in the Field under this Agreement; (ii) as reasonably necessary in filing or prosecuting patent, copyright and trademark applications in accordance with such Party's rights under this Agreement, prosecuting or defending litigation in accordance with this Agreement, complying with applicable governmental regulations with respect to performance under this Agreement, filing Regulatory Filings, obtaining Regulatory Approval or fulfilling post-approval regulatory obligations for the Product in accordance with this Agreement, or otherwise required by Applicable Law; *provided, however*, that if a Party is required by Applicable Law or the rules of any securities exchange or automated quotation system to make any such disclosure of the other Party's Confidential Information it shall, except where impracticable for necessary disclosures (for example, in the event of medical emergency) or not permitted, give reasonable advance notice to the other Party of such disclosure requirement and, in the case of each of the foregoing shall use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; (iii) to advisors (including lawyers and accountants) on a need to know basis, in each case under appropriate confidentiality provisions or professional standards of confidentiality substantially equivalent to those of this Agreement; (iv) to its consultants, agents, actual and bona fide potential investors, lenders or other financing sources, acquirors, licensees, and Sublicensees (in each case, other than an Excluded Party unless the other Party consents thereto in writing) for the purpose of evaluating or carrying out an actual or potential investment, loan, financing, acquisition, license, or collaboration, in each case to the extent reasonably necessary for the purpose and provided that such disclosure is covered by terms of confidentiality and non-use that are materially consistent with those set forth herein (but this clause (iv) shall not apply to Compound Manufacturing Data or Product Manufacturing Data, or Compound-Specific Data or Oral Delivery Data except for Permitted Confidential Disclosures); or (v) to the extent mutually agreed to by the Parties.

10.3. Terms and Conditions Confidential. Neither Party will disclose the terms and conditions of this Agreement except as may be required by Applicable Law. Notwithstanding the foregoing, if a Party is required by Applicable 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 or not permitted, give reasonable advance notice to the other Party of such disclosure requirement and the Parties shall 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 shall seek reasonable confidential treatment for any public disclosure by any such Governmental Authority. Each Party shall have the right to disclose this

Agreement to its actual and bona fide potential investors, lenders or other financing sources, acquirors, licensees, and Sublicensees (in each case, other than an Excluded Party unless the other Party consents thereto in writing) for the purpose of evaluating or carrying out an actual or potential investment, loan, financing, acquisition, license, or collaboration, in each case provided that such disclosure is covered by terms of confidentiality and non-use that are materially consistent with those set forth herein. Each Party shall have the right to issue press releases in regards to this Agreement only with the prior written agreement of the other Party or as required to comply with any Applicable 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). Following issuance of any agreed press releases, each Party may disclose to Third Parties the information contained in such press releases without the need for further approval by the other Party.

10.4. Prior Agreement. This Agreement terminates and supersedes the Mutual Nondisclosure Agreement dated [*] (the *"Prior Agreement"*). All confidential information exchanged between the Parties under the Prior Agreement will be deemed Confidential Information of the disclosing Party and will be subject to the terms of this Agreement as if disclosed hereunder. Each Party's liabilities and indemnification obligations under the Prior Agreement will survive with respect to activities which occurred during the period of time the Prior Agreement was effective.

10.5. Publications and Presentations.

10.5.1. *Publication Strategy*. The JCC shall agree upon a global plan for publishing, presenting and disclosing publicly important Program Data and other key results achieved in connection with the Development and Commercialization of the Product (the *"Publication Plan"*), with the goals of protecting the Parties' ability to obtain patents and other intellectual property protection with respect to such activities, as applicable, to support each Party's financing and business objectives, and to position the Product for Regulatory Approval and successful Commercialization in the Field in the Territory. The JCC shall review and approve the Publication Plan. The Publication Strategy may be updated from time to time, subject to review and approval of the JCC. The Parties shall comply with the Publication Strategy in publicly approved by the JCC. If the JCC cannot agree on a particular press release, publication, presentation, or other public disclosure regarding Program Data, then a Party can decide for itself for its Licensed Territories, subject to Section 10.5.2 (Press Release, Publication and Presentation Process) and the other obligations of this Agreement.

10.5.2. *Press Release, Publication and Presentation Process*. If either Party wishes to publicly disclose or publish (e.g., in a medical or scientific journal) or present publicly (e,g., at scientific meetings such as symposia and other meetings of healthcare professionals, and international, national or regional congresses, conferences or meetings organized by a professional society or organization) any Program Data or other clinical information or key results with respect to the Product, then such Party shall deliver to the other Party a copy of the proposed written press release or publication or an outline of an oral presentation as soon as practicable (and at least [*] for press releases, [*] for other materials) prior to issuance or submission for publication or presentation. The reviewing Party shall have the right to (i) propose modifications to the press release, publication, or presentation for patent reasons, trade secret reasons, confidentiality reasons, or business reasons, and the publishing Party shall remove all Confidential Information of the reviewing Party if requested by the reviewing Party (including Oral Delivery Data or Product Manufacturing Data (if requested by Rani) or Compound-Specific Data or Compound Manufacturing Data (if requested by ProGen)), or (ii) request a reasonable delay in the issuance, publication or presentation in order to protect patentable information. If the reviewing Party requests a delay to protect patentable information, then the publishing Party shall delay issuance, submission or presentation for a period requested, up to [*], to enable patent applications protecting each Party's rights in such information to be filed in accordance with the terms of this Agreement. If the reviewing Party reasonably requests modifications to the press release, publication or presentation to prevent disclosure of trade secrets, confidential information or proprietary business information, then the publishing Party shall edit

such press release, publication or presentation to prevent the disclosure of such information prior to submission of the publication or presentation.

10.5.3. *Non-Program Data*. Notwithstanding anything to the contrary herein, Rani shall have the right to publicly disclose, publish and/or present Oral Delivery Data and ProGen shall have the right to publicly disclose, publish and/or present Compound-Specific Data, in each case without requiring prior consent. For clarity, Rani shall have the right to publish and/or present Program Data aggregated in an anonymized manner with other data regarding the Oral Delivery Technology (e.g., delivery success rate, number of individuals to whom the Device has been administered, Device-related safety data).

10.6. 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.

11. OPT-OUT

11.1. Opt-Out Right. Each Party shall have the right to opt-out of the Collaboration (*"Opt-Out"*) at any time upon prior written notice ("Opt-Out Notice") as set forth in Section 11.3 (Opt-Out Notice).

11.2. Effects of Opt-Out. If one Party (the *"Opt-Out Party"*) delivers an Opt-Out Notice to the other Party (the *"Continuing Party"*), then the following shall occur:

11.2.1. *Transition*. Effective as the Opt-Out Date, the Collaboration shall cease (except as specifically contemplated herein or otherwise reasonably necessary to wind-down Collaboration activities) and the Continuing Party shall have sole right to Develop, conduct regulatory activities for and Commercialize the Product in the Field in the Territory as set forth in this Section 11.2 (Effects of Opt-Out). The Parties shall cooperate to transition the Development (including any ongoing trials, to the extent permitted by Applicable Law), regulatory activities, and Commercialization of Product from the Opt-Out Party to the Continuing Party or its designee. The Opt-Out Party shall take all actions reasonably requested by Continuing Party to facilitate such transition, and the Parties shall conduct such transition expeditiously and as reasonably necessary to minimize disruption in the Development, regulatory activities and Commercialization of Product in the Territory. Each Party shall be responsible [*] in accordance with this Section 11.2.1 (Transition).

11.2.2. *Information Sharing*. Effective as of the Opt-Out Date, the JCC shall be dissolved and the Opt-Out Party shall have no further rights to receive progress reports from the Continuing Party regarding the Product (other than in accordance with any supply agreement as reasonably necessary to support continuing Manufacturing and supply obligations).

11.2.3. *Licenses.* Effective as of the Opt-Out Date, (a) the licenses granted to the Opt-Out Party under Section 8.1 (License to ProGen) if ProGen is the Opt-Out Party or Section 8.2 (License to Rani) if Rani is the Opt-Out Party shall terminate (including, in each case, any sublicenses thereunder), except (i) if [*] in this Agreement or (ii) only to the extent reasonably necessary to conduct the transition under Section 11.2.1 (Transition) and its continuing Manufacturing and supply obligations under Section 11.2.5 (Manufacturing and Supply); (b) the licenses granted to the Continuing Party under Section 8.1 (License to ProGen) if ProGen is the Continuing Party or Section 8.2 (License to Rani) if Rani is the Continuing Party shall become worldwide licenses; (c) the Continuing Party shall have an exclusive license to Program Data (for clarity, ProGen shall continue to have rights to Compound-Specific Data and Compound Manufacturing Data, and Rani shall continue to have rights to Oral Delivery Data and Product Manufacturing Data); and (d) the Continuing Party shall have the sole right to publicly disclose, publish or present Program Data after the Opt-Out Date except as expressly set forth in Section 10.5.3 (Non-Program Data).

11.2.4. *Cost and Profit/Loss Sharing*. The Opt-Out Party shall share (a) all Development Costs and Operating Profit (or Loss) in accordance with Section 7.1 (Development Costs) and 7.2 (Operating Profit or Loss) through the Opt-Out Date, and (b) all costs to complete the conduct of any clinical trials of Product that have been Initiated prior to delivery of the Opt-Out Notice even if the costs are incurred or the trial(s) is/are completed after the Opt-Out Date, provided that such costs shall be in accordance with the Development Plan and Development Budget in effect when the Opt-Out Notice is delivered. Except as set forth in this Section 11.2.4 (Cost and Profit/Loss Sharing), the cost-sharing and Operating Profit (or Loss) sharing between the Parties shall terminate as of the Opt-Out Date for all periods on or after the Opt-Out Date.

11.2.5. *Manufacturing and Supply*. After the Opt-Out Date, the Opt-Out Party shall continue to Manufacture and supply Compound or Device and Product, as applicable, to support the Development, regulatory activities and Commercialization of Product by the Continuing Party in accordance with the terms of a supply agreement then in place or, if not then in place, the Parties shall promptly negotiate in good faith to put a supply agreement in place. The Opt-Out Party shall supply the Compound or Device and Product, as applicable, at cost, and the Continuing Party shall pay the Manufacturing Expenses of the Opt-Out Party therefor. Following [*], then the Continuing Party may require the Opt-Out Party to perform a transfer of the Manufacture of Compound or Device and Product, as applicable, at [*], to a mutually agreed CMO (if such transfer has not already occurred prior to the Opt-Out Date in accordance with Section 6.2 (Manufacturing Transfer)), with [*], by giving written notice thereof to the Opt-Out Party. If such notice is given, the Parties shall reasonably and in good faith agree upon a technology transfer plan and budget for the transfer of such Manufacturing to the selected CMO and then to reasonably promptly effect such transfer in accordance with such plan and budget. The Opt-Out Party shall have the right to secure and put in place reasonable protections for its intellectual property associated with the Manufacturing to be transferred. For clarity, to provide protection for its platform technology, for any transfer of the Manufacturing for Device, Rani may require that [*]. Prior to transfer of Manufacturing to a CMO, the Opt-Out Party shall not have an obligation to [*] (provided the Opt-Out Party reasonably allocates capacity to the Product) unless the Continuing Party agrees [*].

11.2.6. *Limitations.* Notwithstanding any Opt-Out, the obligations set forth in Section 3.6 (Limitations) and 8.3 (Sublicensing) shall continue to apply.

11.2.7. *Royalties*. The Continuing Party shall pay to the Opt-Out Party royalties on Net Sales of the Product made during the Term after the Opt-Out Date at a rate equal to [*] if the Opt-Out Notice if given prior to [*] or [*] if the Opt-Out Notice is given after such time. The terms set forth on Exhibit E shall apply with respect to royalties. If the Continuing Party receives Sublicensing Revenue after the Opt-Out Date with respect to one or more Licensed Territories, then at the Continuing Party's election (which shall be [*]) by written notice to the Opt-Out Party to pay to the Opt-Out Party a percentage of the Sublicensing Revenue in lieu of royalties for the applicable Licensed Territory(ies), which percentage shall be [*] if the Opt-Out Notice was given prior to [*] or [*] if the Opt-Out Notice was given after such time. The compensation due to the Opt-Out Party under this Section 11.2.7 (Royalties), whether royalties or a percentage of Sublicensing Revenue, shall be [*] with respect to Net Sales in a country or Sublicensing Revenue with respect to a country, in each case following the expiration of the Primary Royalty Term in that country.

11.2.8. *Exclusivity*. Effective as of the Opt-Out Date, the obligations under Section 8.7 (Exclusivity) shall terminate for both Parties.

11.2.9. *IP Handling*. The provisions of Article 9 (Intellectual Property) shall continue to apply, except as expressly set forth in this Section 11.2 (Effects of Opt-Out). Effective as of the Opt-Out Date, each Party shall be solely responsible for Product Infringement Claims to the extent arising from its actions or omissions that occur on or after the Opt-Out Date. To the extent Product Infringement Claims arise from actions or omissions occurring prior to the Opt-Out Date, they shall be handled as set forth in Section 9.5 (Defense and Settlement of Product Infringement Claims).

11.2.10. *Other Items*. Effective as of the Opt-Out Date, upon express written request by the Continuing Party, the Opt-Out Party shall do the following as requested by the Continuing Party, (a) to the extent permitted by Applicable Law and requested by Continuing Party, assign any contracts related to Product in the Territory to Continuing Party or its designee (including by requesting and using good-faith efforts to obtain any required consents) to the extent permissible thereunder; (ii) at Opt-Out Party's option, license or assign to the Continuing Party (or its Affiliate or Sublicensee) the trademark(s) used for the Product in the Opt-Out Party's Licensed Territories, for use in Developing and Commercializing the Product in the Field in such Licensed Territories; (iii) if it can be done in a manner that preserves Product quality, sell and transfer to the Continuing Party some or all of the inventory of Product, as requested by the Continuing Party, in possession of the Opt-Out Party (or its Affiliates or Sublicensees) and the Continuing Party shall reimburse the Opt-Out Party the cost of such inventory; and (iv) cooperate to promptly transfer ownership of all Regulatory Filings and Regulatory Approvals specific to the Product, and responsibility for regulatory communication held by the Opt-Out Party or its Affiliates or Sublicensees in the Opt-Out Party's Licensed Territories to the Continuing Party or its designee. In the event that the Parties are not permitted to transfer Regulatory Filings or Regulatory Approvals under clause (iv) above pursuant to Applicable Law, the Parties shall cooperate to establish a right of access and reference to such filings and approvals for the Continuing Party or its designee, and the Opt-Out Party or its Affiliate or Sublicensee shall maintain such filings and approvals, and take any actions reasonably requested by the Continuing Party or its designee with respect thereto, and thereafter the Opt-Out Party shall transfer ownership of all such Regulatory Filings and Regulatory Approvals to the Continuing Party or its designee as and when it becomes permissible to do so.

11.2.11. *Indemnification.* The provisions of Section 14.4 (Product-Related Indemnification after Opt-Out) shall apply.

11.3. Opt-Out Notice. The Opt-Out Notice shall be given (i) at least [*] prior to the Opt-Out Date if the Opt-Out Notice is delivered prior to [*], or (ii) at least [*] prior to the Opt-Out date if the Opt-Out Notice is delivered after [*].

11.4. Mutual Opt-Out. If the Continuing Party delivers an Opt-Out Notice to the first Opt-Out Party during the notice period of the Opt-Out Notice delivered by the first Opt-Out Party (such that both Parties have delivered Opt-Out Notices), then it shall be considered a mutual termination of the Agreement pursuant to Section 15.2.1 (Mutual Termination) and the Parties shall promptly wind down all Collaboration activities as soon as reasonably practicable and in accordance with Applicable Law (and taking into account any ethical obligations in completing or winding-down any ongoing clinical trials or commercialization of the Product).

11.5. Insolvency. A Party shall be deemed to have given an Opt-Out Notice if it suffers an Insolvency Event and the other Party notifies the insolvent Party [*].

11.6. 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 [*] after the receipt of such notice (or [*] with respect to any failure to pay amounts due hereunder), then the other Party shall be permitted to notify the breaching Party [*]; *provided, however*, if the breaching Party notifies the other Party within such [*] period that it disagrees in good faith with such asserted basis for material breach, then [*] unless and until the matter has been finally determined to be a material breach in accordance with Section 15.3 (Governing Law; Arbitration); *provided further* that if a dispute relates to payment, the cure period will only apply with respect to payment of disputed amounts, and not with respect to undisputed amounts.

11.7. Change of Control. A Party shall give the other Party written notice at least [*] in advance of a potential Change of Control or, if such notice is not permissible for confidentiality reasons, then concurrently with the public announcement or disclosure of a proposed (or actual, if no prior announcement was permissible) Change of Control of the first Party. If the Person acquiring control of a Party in a Change of Control (or its

ultimate parent entity) is not a Permitted Party, then the other Party may notify the Party experiencing the Change of Control [*].

11.8. Patent Protection. If on or after [*] of the Effective Date, a Party has no Valid Claims within the Patent Rights of its Licensed IP (i.e., Licensed ProGen Patents with respect to ProGen or Licensed Rani Patents with respect to Rani), but excluding Joint Patent Rights, that Cover the Compound, Device or Product in the US and the European Patent Office, then the other Party may notify the Party without such Patent Rights [*].

12. Representations, Warranties and Covenants

12.1. Mutual Representations and Warranties. Each of the Parties hereby represents and warrants to the other Party as follows:

12.1.1. As of the Effective Date, it is duly organized and validly existing under the laws of its jurisdiction of incorporation or organization and it has full corporate or organizational power and authority and has taken all corporate or organizational action necessary to enter into and perform this Agreement;

12.1.2. As of the Effective Date, 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 to its knowledge as of the Effective Date violate any Applicable Law; and the person or persons executing this Agreement on such Party's behalf have been duly authorized to do so by all requisite corporate or organizational action;

12.1.3. To its knowledge, as of the Effective Date no government authorization, consent, approval, license, exemption of or filing or registration with any court or Governmental Authority, under Applicable Law is or shall be necessary for, or in connection with, the entering into this Agreement or the transaction contemplated by this Agreement, or (except for FDA, EMA or other 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;

12.1.4. It has not granted any right to any Third Party relating to its respective intellectual property, Compound, Device or Product which conflicts with the rights granted to the other Party hereunder; and

12.1.5. As of the Effective Date, it has not been Debarred or the subject of Debarment proceedings.

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

12.2.1. Rani owns or otherwise Controls all of the rights, title and interest in and to the Licensed Rani Patents set forth in Exhibit I, and has the right to grant to ProGen the rights therein purported to be granted to ProGen under this Agreement;

12.2.2. Rani has not received any written communication from any Third Party (i) challenging the validity of Licensed Rani Patents or the effectiveness or ownership of Rani Licensed IP, or (ii) asserting or alleging that the development, manufacture, use or sale of Device misappropriates or infringes the rights of such Third Party;

12.2.3. Rani has not received any written notice that any 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 Device;

12.2.4. To Rani's knowledge, the research, development, manufacture, sale, offer for sale, import or export of the Device as it exists as of the Effective Date does not infringe a valid claim of the Patent Rights, or misappropriate any other intellectual property rights, of any Third Party;

12.2.5. To Rani's knowledge, none of the Licensed Rani Patents are invalid or unenforceable; and

12.2.6. In developing the Device, Rani has not used any employee or permitted subcontractor who is or has been Debarred or is or has been the subject of Debarment proceedings.

12.3. ProGen Representations and Warranties. ProGen hereby represents that, as of the Effective Date:

12.3.1. ProGen owns or otherwise Controls all of the rights, title and interest in and to the Licensed ProGen Patents set forth in Exhibit H and has the right to grant to Rani the rights therein purported to be granted to Rani under this Agreement;

12.3.2. ProGen has not received any written communication from any Third Party (i) challenging the validity of Licensed ProGen Patents or the effectiveness or ownership of ProGen Licensed IP, or (ii) asserting or alleging that the development, manufacture, use or sale of Compound misappropriates or infringes the rights of such Third Party;

12.3.3. ProGen has not received any written notice 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 the Compound;

12.3.4. To ProGen's knowledge, the research, development, manufacture, sale, offer for sale, import or export of the Compound as it exists as of the Effective Date does not infringe a valid claim of the Patent Rights, or misappropriate any other intellectual property rights, of any Third Party;

12.3.5. To ProGen's knowledge, none of the Licensed ProGen Patents are invalid or unenforceable;

12.3.6. In developing the Compound, ProGen has not used any employee or permitted subcontractor who is or has been Debarred or is or has been the subject of Debarment proceedings; and

12.3.7. ProGen has complied, and is in compliance, with and has timely performed its obligations under [*], is in full force and effect and [*].

12.4. Disclaimer of Warranties. EXCEPT AS SET FORTH IN THIS ARTICLE 12 (REPRESENTATIONS, WARRANTIES AND COVENANTS), PROGEN AND RANI EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE COLLABORATION, COMPOUND, DEVICE, PRODUCT, LICENSED IP, THIS AGREEMENT, OR ANY OTHER SUBJECT MATTER RELATING TO THIS AGREEMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND VALIDITY OR NONINFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.

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

12.5.1. It shall not knowingly use in connection with the Development, Manufacture or Commercialization to take place pursuant to this Agreement any employee, consultant or investigator that has been Debarred or is or has been the subject of Debarment proceedings;

12.5.2. It shall carry out its activities hereunder, including Joint Program Activities, in compliance with Applicable Law (including relevant Applicable Law relating to economic sanctions and bribery);

12.5.3. It (and, if applicable, its owners, officers, directors, employees and agents) has not and shall 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) or third party, for the purpose of (i) influencing any act or decision of such official or of such government, (ii) inducing that person to do or omit doing any act in violation of his or her lawful duty, (iii) securing an improper advantage, or (iv) influencing such official to use his or her influence with the government to effect or influence the decision of such government, in order to assist such Party or the Collaboration in obtaining or retaining business for or with or directing business to any person; and

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

12.6. Party Covenants. ProGen hereby covenants to Rani [*].

13. Limitations of Liability; Insurance

13.1. Limitations of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE, 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 13.1 (Limitations of Liability) shall not apply with respect to (i) either Party's indemnification obligations under Article 14 (Indemnification), (ii) breaches of 10.1 (Confidentiality; Exceptions) or 10.2 (Authorized Disclosure), or (iii) gross negligence or willful misconduct of a Party.

13.2. Insurance. During the Term and for [*] thereafter each Party shall obtain and maintain comprehensive general liability insurance covering its obligations and activities hereunder, including products liability insurance and coverage for clinical trials, 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).

14. Indemnification

14.1. Indemnity.

14.1.1. *Indemnification by ProGen*. ProGen shall 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 ProGen's cost and expense, from and against any and all Losses (including reasonable legal expenses and attorneys' fees) incurred by any Rani Indemnitees arising out of any claim, action, lawsuit, or other proceeding (collectively, *"Claims"*) brought against any Rani Indemnitee by a Third Party to the extent such Losses result from (i) the gross negligence or willful misconduct of ProGen, its Affiliates or agents in performing under this Agreement, (ii) a breach by ProGen of this Agreement, including any failure of ProGen's representations or warranties in Section 12.1 (Mutual Representations and Warranties) and 12.3 (ProGen Representations and Warranties) to be true, and (iii) the development, manufacture or commercialization of Compound by ProGen, its Affiliates or sublicensees prior to or outside of the Collaboration; but, in each case above excluding such Losses to the extent they arise from (i), (ii) or (iii) of Section 14.1.2 (Indemnification by Rani) below.

14.1.2. *Indemnification by Rani*. Rani shall defend, indemnify, and hold harmless ProGen, its Affiliates, and their respective directors, officers, employees and agents (solely to the extent acting within their agency) (collectively, *"ProGen Indemnitees"*), at Rani's cost and expense, from and against any and all Losses (including reasonable legal expenses and attorneys' fees) incurred by any ProGen Indemnitees arising out of any Claim brought against any ProGen Indemnitee by a Third Party to the extent such Losses result from (i) the gross negligence or willful misconduct of Rani, its Affiliates or agents in performing under this Agreement, (ii) a breach by Rani of this Agreement, including any failure of Rani's representations or warranties in Section 12.1 (Mutual Representations and Warranties) and 12.2 (Rani Representations and Warranties) to be true, and (iii) the development, manufacture or commercialization of Device by Rani, its Affiliates or sublicensees prior to or outside of the Collaboration; but, in each case above excluding such Losses to the extent they arise from (i), (ii), or (iii) of Section 14.1.1 (Indemnification by ProGen) above.

14.2. Claim for Indemnification. A ProGen Indemnitee or a Rani Indemnitee (the *"Indemnified Party"*) seeking indemnification under this Article 13 (Indemnification) shall 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 14.2 (Claim for Indemnification) shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only 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 shall have exclusive control of the defense and settlement of all Claims for which it is responsible for indemnification and shall 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 shall 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 shall 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 shall reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense.

14.3. Third Party Claims Related to Joint Program Activities. If either Party receives notice of a Claim brought by a Third Party that arises from or is based on any Joint Program Activities, then such Party shall inform the other Party in writing as soon as reasonably practicable, and the Parties shall [*]. Any Joint Program Damages incurred by either Party (or any Rani Indemnitees or ProGen Indemnitees) during the Term or with respect to Joint Program Activities that occurred during the Term, shall be shared such that fifty percent (50%) thereof are borne by Rani and fifty percent (50%) thereof are borne by ProGen, and the Party (or any Rani Indemnitees or ProGen Indemnitees) that has incurred such Joint Program Damages, if not included in any reconciliation calculation and payment pursuant to Section 7.1.3 (Reconciliation/Reimbursement of Development Costs) or included in the Operating Profit (or Loss) calculation pursuant to Section 7.2 (Operating Profit or Loss), shall be reimbursed by the other Party such other Party's fifty percent (50%) share no later than [*] after receipt of reasonable documentation evidencing such amounts.

14.4. Product-Related Indemnification After Opt-Out. Notwithstanding the obligations and cost-sharing set forth in Section 14.3 (Third Party Claims Related to Joint Program Activities), in the event of an Opt-Out, the Continuing Party shall defend, indemnify, and hold harmless the Opt-Out Party and its indemnitees (ProGen Indemnitees or Rani Indemnitees, as the case may be), at the Continuing Party's cost and expense, from and against any and all Losses (including reasonable legal expenses and attorneys' fees) incurred by the Opt-Out Party's Indemnitees (ProGen Indemnitees or Rani Indemnitees, as the case may be) arising out of any Claim brought against any such indemnitee by a Third Party to the extent such Losses result from the Development, Manufacture and Commercialization of the Product conducted by the Continuing Party, its Affiliates or Sublicensees on or after the Opt-Out Date; but, in each case above, excluding such Losses to the extent arising from (i) the Opt-Out Party's (or its Affiliates' or Sublicensees) conduct of transition activities under Section 11.2.1 (Transition), (ii) conduct and completion of any clinical trials of Product Initiated prior to the Opt-Out Date (which shall be treated as still within the Collaboration), or (iii) clauses (i), (ii) or (iii) of the Opt-Out Party's indemnification obligations in Section 14.1.1 (Indemnification by ProGen) or 14.1.2 (Indemnification by Rani), as the case may be. This Section 14.4 (Product-Related Indemnification After Opt-Out) is in addition to, and does not limit, either Party's obligations under Section 14.1 (Indemnity).

15. Term and Termination

15.1. Term. This Agreement shall come into effect as of the Effective Date and shall remain in effect until terminated in accordance with this Article 15 (Term and Termination).

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

15.2.1. *Mutual Agreement*. The Parties may terminate the Agreement at any time upon mutual written agreement. If both Parties Opt-Out, then the Agreement shall terminate.

15.2.2. *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 alleged breaching Party (or its Affiliate) fails to cure such material breach within [*] after the receipt of such notice (or [*] with respect to any failure to pay amounts due hereunder), then the other Party shall be permitted to terminate this Agreement by written notice effective upon delivery; *provided, however*, if the alleged breaching Party notifies the other Party within such [*] period that it disagrees in good faith with such asserted basis for termination, this Agreement shall not terminate unless and until the matter has been finally resolved in accordance with Section 15.3 (Governing Law; Arbitration); *provided further,* that if such dispute relates to payment, the cure period shall only apply with respect to payment of disputed amounts, and not with respect to undisputed amounts.

15.2.3. *Safety Concern*. [*]

15.2.4. *Insolvency*. A Party shall have the right to terminate this Agreement, upon [*] prior written notice thereof to the other Party, if the other Party suffers an Insolvency Event.

15.3. Effect of Termination. In the event of any termination of this Agreement, unless otherwise expressly provided herein: (i) any liabilities previously accrued will survive; (ii) each Party shall return to the other Party or destroy all Confidential Information of the other Party (*provided* that the first Party shall be entitled to retain one (1) copy for archival and compliance purposes, and as required by Applicable Law or regulatory requirement); (iii) the Parties shall promptly wind-down Development and Commercial activities, and if applicable Manufacturing, with respect to Product as expeditiously as reasonably practicable and in compliance with Applicable Law and the duties of a responsible sponsor and industry practice, and the Parties shall continue to abide by the terms of this Agreement with respect thereto until such wind-down is complete, including cost-sharing and sharing of Operating Profit (or Loss); and (iv) all licenses granted to the Parties under Section 8.1 (License to ProGen) and 8.2 (License to Rani) and all sublicenses thereunder granted by the Parties shall terminate (except to the extent, and only for so long as, required to complete the wind-down contemplated in clause (iii) above). Any termination of this Agreement shall be without prejudice to any other right or remedy to which a Party may be entitled. Upon termination of this Agreement, [*].

15.4. Additional Surviving Provisions. In addition and without prejudice to the provisions of Section 15.3 (Effect of Termination) and the provisions that by their nature would be expected to survive termination, in the event of any termination of this Agreement the following provisions shall survive: Sections 7.6 (Audits), [*], 9.4.4 (Joint Patent Rights), 9.5 (Defense and Settlement of Product Infringement Claims) (to the extent applicable to the period prior to termination), 9.7 (Cooperation) (with respect to matters prior to termination), 12.4 (Disclaimer of Warranties), and Articles 10 (Confidentiality and Publications) (except with respect to Section 10.5.1 (Publication Strategy); 13 (Limitations of Liability; Insurance); 14 (Indemnification); 15 (Term and Termination) and 16 (Miscellaneous). In addition, the financial provisions shall apply with respect to any cost-sharing and/or Operating Profit (or Loss) sharing that is applicable to a wind-up of the Collaboration or Joint Program Activities as of the termination date.

16. MISCELLANEOUS

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

16.2. 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 its 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 shall be null and void ab initio. Subject to the foregoing, the rights and obligations of the Parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the Parties.

16.3. Governing Law; Arbitration. This Agreement shall be governed by, and enforced and construed in accordance with, the laws of the State of [*] without regard to any conflicts of law provisions, except as to any issue which depends upon the validity, scope or enforceability of any Patent Right, which issue shall 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 shall try in good faith to settle the same amicably between themselves via their chief executive officers (or their designees). If they fail to reach a resolution amicably within [*] after giving notice of the dispute to the other Party, then either Party may initiate arbitration proceedings with respect to such dispute. Any dispute shall be exclusively and finally settled by arbitration. The seat of arbitration shall be [*] and the rules shall be the [*]. 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 shall 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 shall 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 shall be exclusively conducted in the English language. The United Nations Convention for the International Sale of Goods shall not apply to the transactions contemplated herein.

16.4. 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" shall 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 or Exhibits, unless otherwise specifically provided, shall be construed to refer to Articles, Sections 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 shall be disclosed in the English language.

16.5. 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.

16.6. Entire Agreement. This Agreement, including the attached 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.

16.7. 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, pandemics or epidemics, 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.

16.8. 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.

16.9. 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).

16.10. 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 ProGen: ProGen Co., Ltd.
172, Magokjungang-ro
Gangseo-gu, Seoul, 07789
Republic of Korea
Attention: [*]
Telephone: [*]

If to Rani: Rani Therapeutics, LLC
2051 Ringwood Ave
San Jose, California 95131
Attention: [*]
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 16.10 (Notices).

16.11. 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 ProGen 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.

16.12. 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.

16.13. Third Party Beneficiaries. Except as expressly provided with respect to ProGen Indemnitees or Rani Indemnities in Article 14 (Indemnification), there are no third-party beneficiaries intended hereunder and no Third Party shall have any right or obligation hereunder.

16.14. 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 Collaboration Agreement as of the Effective Date.

PROGEN CO., LTD. **RANI THERAPEUTICS, LLC**

By: /s/ Jong Gyun Kim
Name: Dr. Jonggyun Kim
Title: CEO and the President

Date: 2024-06-17

By: /s/ Talat Imran
Name: Talat Imran
Title: CEO

Date: 6/17/2024

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 A

Development Plan

[*]

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 B

Development Budget

[*]

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 C

Development Costs

"Development Costs" means the following costs incurred by the Parties and their Affiliates in Developing the Product in the Field in the Territory, in each case to the extent incurred in accordance with this Agreement, as follows:

(a) all Out-of-Pocket Costs incurred for activities specified in the Development Plan;

(b) all Out-of-Pocket Costs incurred with respect to preclinical, clinical and nonclinical studies of the Product in the Field in the Territory in accordance with the Development Plan;

(c) (i) Shared Manufacturing Expenses to support Development of the Product in the Field in the Territory; (ii) Out-of-Pocket Costs incurred to purchase or package Third Party comparator or Third Party combination drugs or devices to support Development of the Product in the Field in the Territory; and (iii) Out-of-Pocket Costs of disposal of clinical samples;

(d) all Out-of-Pocket Costs incurred in connection with preparing and submitting Regulatory Filings for the Product, engaging in regulatory meetings and correspondence with Regulatory Agencies with respect to Product, supporting regulatory inspections specifically associated with the Product, and obtaining and maintaining Regulatory Approvals for Product in the Field;

(e) all Out-of-Pocket Costs attributable to establishing, updating and maintaining a global safety database for Product; and

(f) any other Out-of-Pocket Costs incurred that are explicitly included in the Development Budget.

Development Costs shall exclude [*] not previously agreed to by the Parties as part of the Development Plan or Development Budget and any other cost not included in Development Costs, including by way of example, costs attributable to the development or manufacture of Compound, Device or Oral Delivery Technology independent of or outside of the Collaboration, costs attributable to general corporate activities, executive management, investor relations, treasury services, business development, corporate government relations, external financial reporting and other overhead unless otherwise agreed to in writing by the Parties. Development Costs may include other costs from time to time as mutually agreed by the Parties.

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 D

Operating Profit or Loss Calculation

Unless otherwise mutually agreed by the Parties, Operating Profit (or Loss) from Product in the Territory shall be calculated in accordance with this Exhibit. If a Party licenses rights to a Sublicensee, the Parties shall reasonably consider in good faith whether any changes are appropriate or required (e.g., additional time) to accommodate sharing and reporting of financial information under the Agreement.

For each Calendar Quarter during which any of the following costs are incurred or revenues are recognized by a Party or its Affiliate with respect to Joint Program Activities or the Product, each Party shall report to the JCC, within [*] after the end of each such Calendar Quarter: its Net Sales of Product or Other Income attributable to such Calendar Quarter, and Shared Manufacturing Expenses to support Commercialization, Other Expenses and Commercialization Costs incurred during such period, in each case in such reasonable detail and format as is established by the JCC (or relevant subcommittee) (each, a *"Post-Commercialization Report"*).

Within [*] after receipt of the Post-Commercialization Reports, the finance contacts of each Party shall confer and agree upon in writing a consolidated financial statement (i) setting forth the Operating Profit (or Loss) for such Calendar Quarter, as the case may be, for the Product in the Territory, and (ii) calculating each Party's share of such Operating Profit (or Loss). Within [*], Rani or ProGen, as applicable, shall make a payment to the other Party, so that each of Rani and ProGen has been compensated for its respective share of such Operating Profit, or has borne its respective share of such Operating Loss, as applicable, with respect to the Product in such Calendar Quarter; *provided*, *however*, that in the event of any disagreement with respect to the calculation of such payment, any undisputed portion of such payment shall be paid in accordance with the foregoing timetable and the remaining, disputed portion shall be paid within [*] after the date on which the Parties, using good faith efforts, resolve the dispute. In addition, following the Effective Date, each Party shall consider in good faith other reasonable procedures proposed by the other Party for sharing financial information in order to permit each Party to close its books periodically in a timely manner.

Sublicensing Revenue shall be shared equally by the Parties as part of Other Income. For clarity, [*], unless otherwise mutually agreed by the Parties in writing.

"Net Sales" means, with respect to a given period and jurisdiction, the gross invoiced sales price for the Product sold by or on behalf of a Party or its Affiliates (each, *"Seller"*) hereunder to Third Parties during such period, less the following deductions with respect to such sales to the extent that such amounts are either included in the billing as a line item as part of the gross amount invoiced, or otherwise documented in accordance with Accounting Standards to be specifically attributable to actual sales of such Product:

(i) normal and customary trade, cash, prompt payment, and quantity discounts actually allowed and taken directly by the Third Party;

(ii) rebates, refunds, and chargebacks (or equivalents thereof) granted to federal, state, provincial, local or other governments, their agencies or Third Party payors, administrators or contractors, including managed health organizations;

(iii) credits and allowances (actually allowed or paid) for product replacement, whether cash or trade;

(iv) non-recoverable sales taxes, excise taxes, tariffs, and duties (excluding taxes when assessed on income derived from sales); and

(v) reasonable transportation charges relating to the Product, including handling charges and insurance premiums relating thereto to the extent included as a separate entry on the invoice for such product (*provided, however*, that the total of all items in this clause (v) shall [*] of the gross sales price for the relevant period);

in each case, to the extent related to sales of the Product in the Territory.

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 [*].

Any disposal of a given Product at no charge for, or use of such Product without charge in, clinical, nonclinical or preclinical trials, given as free samples, or distributed at no charge to patients unable to purchase the same shall not be included in Net Sales.

Except as set forth in the preceding paragraph, any transaction, disposition, or other dealing involving Product between a Seller and a Third Party end user that is made at less than fair market value is deemed to have been made at fair market value, and the fair market value of the transaction, disposition, or other dealing shall be added to and deemed part of the Net Sales and shall be included in the calculation of Operating Profit (or Loss) under this Agreement.

A Seller shall not sell any Product in combination with, as part of a bundle or risk sharing scheme with, or as a combination therapy with other products, or offer packaged arrangements to customers that include a Product, in such a manner as to disproportionately discount the selling price of the Product.

Upon any sale or other disposition of Product for any consideration other than exclusively monetary consideration on bona fide arms'-length terms, then for purposes of calculating Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for money at the average sales price of the relevant presentation of the Product in arm's length transactions during the applicable reporting period generally achieved for such presentation of the Product in the country in which such sale or other disposition occurred when such Product is sold alone and not with other products.

In no event shall any particular amount identified above be deducted more than once in calculating Net Sales. Sales of a Product between Sellers for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Product to a Third Party shall be included within the computation of Net Sales.

Net Sales and the enumerated elements of Net Sales calculations shall be determined in accordance with Accounting Standards, applied on a consistent basis.

Where a Product is sold together with other therapeutically active ingredient(s) for a single price (regardless of their packaging) (a *"Bundle"*), then for the purposes of calculating the Net Sales under this Agreement, the Net Sales attributable to Product will be determined by multiplying the Net Sales amount for the Bundle during the applicable reporting period, calculated as set forth hereunder, by the fraction A/(A+B), where: A is the weighted average sale price of the Product during the applicable reporting period when such Product is sold alone, and Y is the weighted average sale price of the other therapeutically active ingredient(s) in the Bundle during the applicable reporting period when sold alone, in each case in the same dosage and dosage form and in the same country as the Bundle during the applicable reporting period. In the event that the Product or one or more of the other therapeutically active ingredient(s) in the Bundle are not sold separately, the Parties will confer in good faith to determine an equitable fair market price to apply to such Product.

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 E

Royalties

A. Continuing Party Net Sales. *"Continuing Party Net Sales"* means, with respect to a given period and jurisdiction, the gross invoiced sales price for the Product sold by or on behalf of the Continuing Party, its Affiliates or Sublicensees (each, a *"Continuing Seller"*) hereunder to Third Parties during such period, less the following deductions with respect to such sales to the extent that such amounts are either included in the billing as a line item as part of the gross amount invoiced, or otherwise documented in accordance with Accounting Standards to be specifically attributable to actual sales of such Product:

(i) normal and customary trade, cash, prompt payment, and quantity discounts actually allowed and taken directly by the Third Party;

(ii) rebates, refunds, and chargebacks (or equivalents thereof) granted to federal, state, provincial, local or other governments, their agencies or Third Party payor, administrator or contractor, including managed health organizations;

(iii) credits and allowances (actually allowed or paid) for product replacement, whether cash or trade;

(iv) non-recoverable sales taxes, excise taxes, tariffs, and duties (excluding taxes when assessed on income derived from sales); and

(v) reasonable transportation charges relating to the Product, including handling charges and insurance premiums relating thereto to the extent included as a separate entry on the invoice for such product (*provided, however*, that the total of all items in this clause (v) will [*] of the gross sales price for the relevant period);

in each case, to the extent related to sales of the Product in the Field in the Territory.

Any disposal of a given Product at no charge for, or use of such Product without charge in, clinical or preclinical trials, given as free samples, or distributed at no charge to patients unable to purchase the same will not be included in Continuing Party Net Sales.

Except as set forth in the preceding paragraph, any transaction, disposition, or other dealing involving Product between the Continuing Seller and Third Party that is made at less than fair market value is deemed to have been made at fair market value, and the fair market value of the transaction, disposition, or other dealing will be added to and deemed part of the Continuing Party Net Sales and will be included in the calculation of royalties under this Agreement.

The Continuing Party will not sell any Product in combination with, as part of a bundle or risk sharing scheme with, or as a combination therapy with other products, or offer packaged arrangements to customers that include a Product, in such a manner as to disproportionately discount the selling price of the Product.

Upon any sale or other disposition of Product for any consideration other than exclusively monetary consideration on bona fide arms'-length terms, then for purposes of calculating Continuing Party Net Sales under this Agreement, such Product will be deemed to be sold exclusively for money at the average sales price of the relevant presentation of the Product in arm's length transactions during the applicable reporting period generally achieved for such presentation of the Product in the country in which such sale or other disposition occurred when such Product is sold alone and not with other products.

In no event will any particular amount identified above be deducted more than once in calculating Continuing Party Net Sales. Sales of a Product between Continuing Party and its Affiliates or Sublicensees for resale will be excluded from the computation of Continuing Party Net Sales, but the subsequent resale of such Product to a Third Party by such Affiliate or Sublicensee will be included within the computation of Continuing Party Net Sales.

Continuing Party Net Sales and the enumerated elements of Continuing Party Net Sales calculations shall be determined in accordance with Accounting Standards, applied on a consistent basis.

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 [*].

B. Primary Royalty Term. *"Primary Royalty Term"* means, on a country-by-country basis, that period from the First Commercial Sale of the Product following Regulatory Approval in such country (or, if later, the Opt-Out Date) until expiration of the last to expire Patent within the Opt-Out Party's Licensed IP that has one or more Valid Claims that would, but for the licenses granted under this Agreement, be infringed by the manufacture, use, sale, offer to sell or import of such Product in the country in which such manufacture, use, sale, offer to sell or import occurs by the Continuing Party, its Affiliates or Sublicensees.

C. Bundle. Where a Product is sold in a Bundle, then for the purposes of calculating the Net Sales under this Agreement, the Continuing Party Net Sales attributable to Product shall be determined by multiplying the Continuing Party Net Sales amount for the Bundle during the applicable reporting period, calculated as set forth hereunder, by the fraction A/(A+B), where: A is the weighted average sale price of the Product during the applicable reporting period when such Product is sold alone, and Y is the weighted average sale price of the other therapeutically active ingredient(s) in the Bundle during the applicable reporting period when sold alone, in each case in the same dosage and dosage form and in the same country as the Bundle during the applicable reporting period. In the event that the Product or one or more of the other therapeutically active ingredient(s) in the Bundle are not sold separately, the Parties shall confer in good faith to determine an equitable fair market price to apply to such Product.

D. Payments and Reports. Beginning with the Calendar Quarter in which the later of the Opt-Out Date or the First Commercial Sale of Product occurs and for each Calendar Quarter thereafter, royalty payments and reports of the sale of Product for each Calendar Quarter shall be calculated and delivered by the Continuing Party to the Opt-Out Party within [*] days after the end of each such Calendar Quarter. Each payment of royalties shall be accompanied by a report of Net Sales of Product stating: (i) Continuing Party Net Sales of Product by or on behalf of the Continuing Party, its Affiliates or Sublicensees during the applicable Calendar Quarter (detailed country-by-country with gross invoiced amounts, deductions and Continuing Party Net Sales); and (ii) a calculation of the royalty payment due from the Continuing Party hereunder for such Calendar Quarter. For any reports which contain currency conversions, upon request of the Opt-Out Party, the Continuing Party shall provide the details and background information used to calculate such conversions. For any Licensed Territories for which the Continuing Party has elected to pay a portion of Sublicensing Revenue instead of royalties on Continuing Party Net Sales pursuant to Section 11.2.7 (Royalties), the terms in this Section D shall apply with respect to payment and reporting of such portion of Sublicensing Revenue in the same manner as for royalties (except that the calculation reported shall be with respect to the portion of Sublicensing Revenue due instead of Continuing Party Net Sales, and no reporting of Continuing Party Net Sales shall be required for such Licensed Territories if no royalty is being paid with respect thereto).

E. No Wrongful Reductions. The Continuing Party shall not attempt to reduce compensation rightly due to the Opt-Out Party hereunder by shifting compensation otherwise payable to the Continuing Party from a Third Party with respect to Product to another product or service for which no royalties (or Sublicensing Revenue) are payable by it hereunder.

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 F

Licensed Territories

The Licensed Territories for each Party are as follows:

For Rani: US, Canada, Europe (including United Kingdom), and Australia

For ProGen: Rest of the world (the countries/territories other than those assigned to Rani above)

For clarity, *"Europe"* means the territory encompassed as of the Effective Date by the countries listed below and includes all member states within the European Union:

Albania, Andorra, Armenia, Austria, Azerbaijan, Belarus, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Ireland, Italy, Kazakhstan, Kosovo, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Monaco, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom, Vatican City.

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 G

Dosage Forms

[*]

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 H

Licensed ProGen Patents

[*]

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 I

Licensed Rani Patents

[*]

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 J

Permitted Confidential Disclosures

The following are Permitted Confidential Disclosures of each Party:

[*]

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 K

FTE Rate Schedule

[*]

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 L

Corresponding Contacts

[*]

Alliance Managers and JCC membership to be finalized promptly following the Effective 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 6, 2024

/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 6, 2024

/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, 2024, 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 6, 2024

In Witness Whereof, the undersigned have set their hands hereto as of the 6th day of August, 2024

/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.