UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, DC 20549

FORM 10-Q

(Mark One) ☑ QUARTERLY REPORT PURSUANT TO SI	ECTION 13 OR 15(d) OF	THE SECURITIES EXC	HANGE ACT OF 19	34
For the quar	terly period ended Septer	mber 30, 2025		
•	OR			
☐ TRANSITION REPORT PURSUANT TO SI	ECTION 13 OR 15(d) OF	THE SECURITIES EXC	HANGE ACT OF 19	34
For the transition perio	od from	to		
Comm	mission File Number: 001	-40672		
			T	
RANI THERAPI	EUTICS H	OLDINGS	, INC.	
(Exact Name of	of Registrant as Specified	in its Charter)		
Delaware (State or other jurisdiction of incorporation or organization) 2051 Ringwood Avenue		86-3114789 (I.R.S. Employer Identification No.)		
San Jose, California (Address of principal executive offices)		95131 (Zip Code)		
Registrant's telephor	ne number, including area	a code: (408) 457-3700		
Securities registered pursuant to Section 12(b) of th	e 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 N		
Indicate by check mark whether the registrant (1) h: Act of 1934 during the preceding 12 months (or for such sh to such filing requirements for the past 90 days. Yes ⊠	orter period that the registrant			
Indicate by check mark whether the registrant has sr Rule 405 of Regulation S-T ($\$232.405$ of this chapter) during submit such files). Yes \boxtimes No \square				
Indicate by check mark whether the registrant is a la company, or an emerging growth company. See the definitie "emerging growth company" in Rule 12b-2 of the Exchange	ons of "large accelerated filer,			
Large accelerated filer Non-accelerated filer Emerging growth company ⊠			lerated filer ler reporting company	
If an emerging growth company, indicate by check with any new or revised financial accounting standards prov	•		sition period for complyi	ing
Indicate by check mark whether the registrant is a si	hell company (as defined in R	ule 12b-2 of the Exchange Act). Yes □ No ⊠	
As of October 31, 2025, the registrant had 97,541,2 shares of Class B common stock, \$0.0001 par value per sha outstanding. Certain holders of units of the registrant's cons Class B common stock can exchange their units of Rani The	re, outstanding and no shares solidated subsidiary, Rani The	of Class C common stock, \$0.0 rapeutics, LLC, who do not hol	001 par value per share, d shares of the registrant	

Table of Contents

Special No	te Regarding Forward-Looking Statements	Page 3
PART I.	FINANCIAL INFORMATION	
	RANI THERAPEUTICS HOLDINGS, INC.	
Item 1.	<u>Financial Statements (Unaudited)</u>	5
	Condensed Consolidated Balance Sheets	5
	Condensed Consolidated Statements of Operations	6
	Condensed Consolidated Statements of Comprehensive Loss	7
	Condensed Consolidated Statements of Changes in Stockholders' (Deficit)/Equity	8
	Condensed Consolidated Statements of Cash Flows	10
	Notes to Unaudited Condensed Consolidated Financial Statements	11
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	25
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	35
Item 4.	Controls and Procedures	35
PART II.	OTHER INFORMATION	36
Item 1.	<u>Legal Proceedings</u>	36
Item 1A.	Risk Factors	36
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	38
Item 3.	<u>Defaults Upon Senior Securities</u>	38
Item 4.	Mine Safety Disclosures	38
Item 5.	Other Information	38
Item 6.	<u>Exhibits</u>	39
Signatures		40

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, timing, 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 plans relating to commercializing our product candidates, if approved;
- our ability to selectively enter into strategic partnership and the expected potential benefits thereof, including our collaboration with Chugai Pharmaceuticals Co. Ltd.;
- the implementation of our strategic plans for our business and product candidates;
- our ability to continue to scale and optimize our manufacturing processes, including 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 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 maintain the listing of our Class A common stock on the Nasdaq Global Market;
- our ability to realize savings from any restructuring plans or cost-containment measures;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- 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 31, 2025. 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)

	Se	eptember 30,	I	December 31,
		2025 Unaudited)		2024
Assets	,			
Current assets:				
Cash and cash equivalents	\$	4,144	\$	3,762
Contract asset		_		428
Marketable securities		_		23,877
Prepaid expenses and other current assets		811		1,677
Total current assets		4,955		29,744
Property and equipment, net		922		1,548
Operating lease right-of-use asset		4,017		5,096
Other assets		245		246
Total assets	\$	10,139	\$	36,634
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	\$	2,467	\$	1,359
Accrued expenses and other current liabilities		2,091		2,073
Current portion of long-term debt		13,537		15,000
Current portion of operating lease liability		1,049		1,459
Total current liabilities		19,144		19,891
Long-term debt, less current portion		_		9,613
Operating lease liability, less current portion		2,968		3,637
Total liabilities		22,112		33,141
Commitments and contingencies (Note 12)				
Stockholders' equity:				
Preferred stock, \$0.0001 par value - 20,000 shares authorized; none issued and				
outstanding as of September 30, 2025 and December 31, 2024		_		_
Class A common stock, \$0.0001 par value - 800,000 shares authorized; 47,941 and				
33,430 issued and outstanding as of September 30, 2025 and December 31, 2024,				
respectively		4		3
Class B common stock, \$0.0001 par value - 40,000 shares authorized; 23,970 and				
23,972 issued and outstanding as of September 30, 2025 and December 31, 2024,				
respectively		2		2
Class C common stock, \$0.0001 par value - 20,000 shares authorized; none issued and				
outstanding as of September 30, 2025 and December 31, 2024		_		_
Additional paid-in capital		114,406		104,889
Accumulated other comprehensive gain		3		5
Accumulated deficit		(122,275)		(102,907)
Total stockholders' (deficit)/equity attributable to Rani Therapeutics Holdings, Inc.		(7,860)		1,992
Non-controlling interest		(4,113)		1,501
Total stockholders' (deficit)/equity		(11,973)		3,493
Total liabilities and stockholders' equity	\$	10,139	\$	36,634

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

RANI THERAPEUTICS HOLDINGS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)
(Unaudited)

	Thre	e Months End	led Se		Niı	eptember 30,		
		2025		2024		2025		2024
Contract revenue	\$	_	\$	_	\$	172	\$	_
Operating expenses								
Research and development		3,221		6,172		15,296		19,872
General and administrative		4,036		5,627		14,651		18,484
Total operating expenses	\$	7,257	\$	11,799	\$	29,947	\$	38,356
Loss from operations		(7,257)		(11,799)		(29,775)		(38,356)
Other income (expense), net								
Interest income and other, net		68		414		443		1,403
Interest expense and other, net		(725)		(1,337)		(2,544)		(3,909)
Net loss	\$	(7,914)	\$	(12,722)	\$	(31,876)	\$	(40,862)
Net loss attributable to non-controlling interest		(2,502)		(5,939)		(12,508)		(19,791)
Net loss attributable to Rani Therapeutics Holdings, Inc.	\$	(5,412)	\$	(6,783)	\$	(19,368)	\$	(21,071)
Net loss per Class A common share attributable to Rani								
Therapeutics Holdings, Inc., basic and diluted	\$	(0.12)	\$	(0.24)	\$	(0.50)	\$	(0.78)
Weighted-average Class A common shares outstanding—basic								
and diluted		46,444		28,836	_	38,856	_	27,071

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

	Thre	e Months End	led S	eptember 30,	Nir	ne Months End	ptember 30,	
	2025		2024		2025			2024
Net loss	\$	(7,914)	\$	(12,722)	\$	(31,876)	\$	(40,862)
Other comprehensive loss								
Net unrealized (loss) gain on marketable securities		_		24		(5)		37
Comprehensive loss	\$	(7,914)	\$	(12,698)	\$	(31,881)	\$	(40,825)
Comprehensive loss attributable to non-controlling interest		(2,502)		(5,928)		(12,510)		(19,774)
Comprehensive loss attributable to Rani Therapeutics Holdings, Inc.	\$	(5,412)	\$	(6,770)	\$	(19,371)	\$	(21,051)

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

	Class A Comm	on Stock	Class B Comn	non Stock					
	Shares	Amount	Shares	Amount	Additional Paid In Capital	Accumulated Other Comprehensive Gain	Accumulated Deficit	Non-Controlling Interest	Total Stockholders' (Deficit)/Equity
Balance at December 31, 2024	33,430	\$ 3	23,972	\$ 2	\$ 104,889	\$ 5	\$ (102,907)	\$ 1,501	\$ 3,493
Issuance of common stock under employee equity plans, net of shares withheld for tax settlement	140	_		_	(23)	_	· · ·		(23)
Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC	_	_	_	_	1	_	_	(1)	_
Stock-based compensation	_	_	_	_	2,241	_	_	1,684	3,925
Net loss	_	_	_	_		_	(7,264)	(5,474)	(12,738)
Other comprehensive loss						(3)		(3)	(6)
Balance at March 31, 2025	33,570	\$ 3	23,972	\$ 2	\$ 107,108	\$ 2	\$ (110,171)	\$ (2,293)	\$ (5,349)
Exercise of warrants issued in connection with the October 2024 and July 2024 Securities Purchase									
Agreement, net of issuance costs of \$340	5,419	_	_	_	3,937	_	_	_	3,937
Warrant issued for services provided	_	_	_	_	152	_	_	_	152
Issuance of common stock under employee equity plans, net of shares withheld for tax settlement	44	_	_	_	(8)	_	_	_	(8)
Issuance of common stock under employee stock	0.7				47				46
purchase plan	97	_	_	_	46	_	_	_	46
Effect of exchanges of Paired Interests and non- corresponding Class A Units of Rani LLC Non-controlling interest adjustment for changes in	107		(2)			_		_	_
proportionate ownership in Rani LLC					(1,963)			1,963	
Stock-based compensation		_		_	2,008		_	1,284	3.292
Net loss					2,008	_	(6,692)	(4,532)	(11,224)
Other comprehensive loss						1	(0,072)	(4,332)	(11,224)
Balance at June 30, 2025	39,237	\$ 3	23,970	\$ 2	\$ 111,280	\$ 3	\$ (116,863)	\$ (3,578)	\$ (9,153)
Issuance of common stock and pre-funded warrants in connection with the July 2025 Securities Purchase									
Agreement, net of issuance costs of \$189	7,500	1	_	_	2,810	_	_	_	2,811
Exercise of pre-funded warrants	1,161	_	_	_	_	_	_	_	_
Warrant modification expense	_	_	_	_	15	_	_	_	15
Issuance of common stock under employee equity plans, net of shares withheld for tax settlement	43	_	_	_	(7)	_	_	_	(7)
Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC	_				(1,163)			1,163	
Stock-based compensation					1.539			804	2,343
Issuance costs related to the October 2024 and July	_	_	_	_	,	_	_	804	
2025 Securities Purchase Agreement	_	_	_	_	(68)	_	_	_	(68)
Net loss							(5,412)	(2,502)	(7,914)
Balance at September 30, 2025	47,941	\$ 4	23,970	\$ 2	\$ 114,406	\$ 3	\$ (122,275)	\$ (4,113)	\$ (11,973)

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

	Class A Common Stock Class B Common Stock				Accumulated											
	Shares	Amour	ıt Shar	es	Amo	ount		tional Paid Capital		cumulated Other prehensive Loss			umulated Deficit	Non- ntrolling interest	Stoc	Total kholders' Equity
Balance at December 31, 2023	26,036	\$	3 24	,116	\$	2	\$	85,762	\$	(1	(2)	\$	(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	\$	(1	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	\$	1	(5)	\$	(87,177)	\$ 2,715	\$	5,550
Issuance of common stock in connection with the July											_					
Securities Purchase Agreement, net of issuance costs of																
\$1,117	2,800		_	_		_		8,883		-	_		_	_		8,883
Exercise of pre-funded warrants	447		_	_		_		´ —		-	_		_	_		´—
Issuance of common stock under employee equity																
plans, net of shares withheld for tax settlement	71		_	_		_		(1)		-	_		_	_		(1)
Non-controlling interest adjustment for changes in																
proportionate ownership in Rani LLC	_		_	_		_		(4,010)		-	_		_	4,010		_
Stock-based compensation	_		_	_		_		2,183		-	_		_	1,858		4,041
Net loss	_		_	_		_		_			_		(6,783)	(5,939)		(12,722)
Other comprehensive gain											13			11		24
Balance at September 30, 2024	29,807	\$	3 24	,116	\$	2	\$	97,067	\$		8	\$	(93,960)	\$ 2,655	\$	5,775

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

	Nine Months Ended September				
		2025	•	2024	
Cash flows from operating activities					
Net loss	\$	(31,876)	\$	(40,862)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Stock-based compensation expense		9,560		12,040	
Depreciation and amortization		714		762	
Non-cash operating lease expense		1,427		1,332	
Warrant issued for services provided		152		_	
Warrant modification expense		15		_	
Amortization of debt discount and issuance costs		174		174	
Net accretion and amortization of investments in marketable securities		(158)		(940)	
Loss on disposal of property and equipment		_		65	
Changes in operating assets and liabilities:					
Contract asset		428		_	
Prepaid expenses and other current assets		866		341	
Accounts payable		1,108		918	
Accrued expenses and other current liabilities		8		61	
Deferred revenue		_		600	
Operating lease liabilities		(1,426)		(1,332)	
Net cash used in operating activities		(19,008)		(26,841)	
Cash flows from investing activities					
Proceeds from maturities of marketable securities		26,750		57,250	
Purchases of marketable securities		(2,720)		(39,725)	
Purchases of property and equipment		(88)		(237)	
Net cash provided by investing activities		23,942		17,288	
Cash flows from financing activities					
Proceeds from exercise of warrants for common stock, net of issuance costs of \$408		3,869		_	
Proceeds from issuance of common stock and pre-funded warrants in connection with the July					
2025 Securities Purchase Agreement, net of issuance costs of \$189		2,811		_	
Proceeds from issuance of common stock and pre-funded warrants in connection with the July					
2024 Securities Purchase Agreement, net of issuance costs of \$1,117		_		8,883	
Issuance of common stock under employee stock purchase plan		46		221	
Proceeds from employee stock purchase plan		10		99	
Proceeds from the exercise of stock options		_		51	
Tax withholdings paid on behalf of employees for net share settlement		(38)		(38)	
Repayment of debt		(11,250)		(1,250)	
Net cash (used in)/provided by financing activities		(4,552)		7,966	
Net increase/(decrease) in cash, cash equivalents and restricted cash equivalents		382		(1,587)	
Cash, cash equivalents and restricted cash equivalents, beginning of period		4,262		6,364	
Cash, cash equivalents and restricted cash equivalents, end of period	\$	4,644	\$	4,777	
Supplemental disclosures of non-cash investing and financing activities					
Interest income receivable included in prepaid expenses and other current assets	\$	13	\$	29	
Right-of-use assets obtained in exchange for new operating lease liabilities	\$		\$	4.731	
Exchanges of non-corresponding Class A Units of Rani LLC	\$	63	\$	298	
		03	\$		
Remeasurement of operating lease right-of-use assets	\$		\$	589	

RANI THERAPEUTICS HOLDINGS, INC. NOTES TO THE 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.

Organizational Transactions

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 Fifth Amended and Restated Limited Liability Company Agreement of Rani LLC (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 September 30, 2025, 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 1,124,194 shares of the Company's Class A common stock.

Liquidity and Going Concern

The Company has incurred recurring losses since its inception, including net losses of \$31.9 million for the nine months ended September 30, 2025. As of September 30, 2025, the Company had an accumulated deficit of \$122.3 million, and for the nine months ended September 30, 2025, had negative cash flows from operations of \$19.0 million. As of September 30, 2025, cash, cash equivalents, and restricted cash equivalents totaled \$4.6 million. While these factors had raised substantial doubt about our ability to continue as a going concern, after September 30, 2025, as disclosed in more detail in Note 16, the Company entered into various financing agreements and a license and collaboration agreement in October 2025. The Company believes that the available cash in the Company's bank accounts, the proceeds from the closing of the Private Placement, the upfront payment from the Collaboration and License Agreement with Chugai, the proceeds received from Series D Warrant exercises, and impact of the Debt Conversion by the Lender are sufficient to alleviate substantial doubt about the Company's ability to continue as a going concern for at least the next twelve months from the date the condensed consolidated financial statements are issued.

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, 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.

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").

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 nine months ended September 30, 2025, are not necessarily indicative of the results that may be expected for the year ending December 31, 2025 or for any future period.

The consolidated balance sheet as of December 31, 2024 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 2024 consolidated financial statements and notes included in the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2025.

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, 2024. Except as noted below, there have been no material changes in the Company's significant accounting policies during the nine months ended September 30, 2025.

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 nine months ended September 30, 2025 and 2024:

	Ni	Nine Months Ended September 30					
		2025	2024				
Cash and cash equivalents	\$	4,144	\$	4,277			
Restricted cash equivalents		500		500			
Total cash, cash equivalents and restricted cash equivalents	\$	4,644	\$	4,777			

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("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, 2025 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 consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40) ("ASU 2024-03"). ASU 2024-03 provides disaggregated information about certain income statement costs and expenses. The guidance is effective for the Company's annual periods beginning January 1, 2027, with early adoption permitted. The Company is evaluating the impact of this guidance on its consolidated financial statements and related disclosures.

3. Cash Equivalents, Restricted Cash Equivalents and Marketable Securities

The following tables summarize 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 September 30, 2025									
		nortized Cost		alized ains		alized sses		timated ir Value		
Current assets:										
Cash equivalents:										
Money market funds	\$	2,323	\$	_	\$	_	\$	2,323		
Total cash equivalents		2,323						2,323		
Restricted cash equivalents:		500						500		
Total cash equivalents and restricted cash equivalents	\$	2,823					\$	2,823		
			As	of Decem	ber 31,	2024				
		nortized Cost		alized	Unrealized Losses		Estimated Fair Value			
Current assets:		Cost		ams		3303		ii value		
Cash equivalents:										
Money market funds	\$	404	\$	_	\$	_	\$	404		
Total cash and cash equivalents		404						404		
Restricted cash equivalents:										
Money market funds		500		_		_		500		
Total cash equivalents and restricted cash equivalents		904		_				904		
Marketable securities:										
U.S. Treasuries and agencies		24,871		5		_		24,876		
Total cash equivalents, restricted cash equivalents and										
marketable securities	\$	25,775	\$	5	\$		\$	25,780		

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 September 30, 2025, 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 September 30, 2025. As of September 30, 2025 and December 31, 2024, interest income receivable recorded as a component of prepaid expenses and other current assets on the condensed consolidated balance sheet was de minimis.

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 indicate the level of inputs used in such measurements (in thousands):

	As of September 30, 2025								
		Level 1	I	evel 2	Level 3			Total	
Assets:									
Cash equivalents:									
Money market funds	\$	2,323	\$	_	\$ -	_	\$	2,323	
Restricted cash equivalents:									
Money market funds		500		_	-	_		500	
Marketable securities									
U.S. Treasuries and agencies		_		_	-	_		_	
Total assets	\$	2,823	\$		\$		\$	2,823	
							_		
			A:	of Decemb	per 31, 2024				
		evel 1		of December	Der 31, 2024 Level 3			Total	
Assets:		evel 1				_	_	Total	
Assets: Cash equivalents:	_1	evel 1				_		Total	
	\$	evel 1 404					\$	Total 404	
Cash equivalents:			L		Level 3	_	\$		
Cash equivalents: Money market funds			L		Level 3		\$		
Cash equivalents: Money market funds Restricted cash equivalents:		404	L		Level 3	_	\$	404	
Cash equivalents: Money market funds Restricted cash equivalents: Money market funds		404	L		Level 3		\$	404	

Level 1 financial instruments are comprised of investments in money market funds. 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):

	Sept	tember 30,	December 31		
		2025		2024	
Accrued interest	\$	1,255	\$	931	
Accrued professional fees		138		107	
Payroll and related costs		154		353	
Accrued rent		334		329	
Accrued preclinical and clinical trial costs		77		70	
Other		133		283	
Total accrued expenses and other current liabilities	\$	2,091	\$	2,073	

6. Evaluation and Collaborative Arrangements

Evaluation Arrangement

In August 2024, the Company entered into a contract with Chugai Pharmaceutical Co., Ltd. ("Chugai") to conduct evaluation services of certain Chugai compounds for oral delivery using the RaniPill HC, which was concluded to be a single performance obligation with an enforceable right to payment. Chugai paid the Company an up-front payment of \$0.6 million upon execution of the contract. Upon completion of the evaluation services, in April 2025, the Company was paid a final \$0.6 million for an

aggregate total of \$1.2 million due under the contract. For the three and nine months ended September 30, 2025, \$0 and \$0.2 million in contract revenue were recognized for evaluation services performed, respectively.

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 parties share responsibility for the development of RT-114 worldwide, with the Company leading such development for preclinical activities through Phase 1 clinical trials. After initiation of the first Phase 2 clinical trial, the Company will lead development and commercialization of the Product in the United States, Canada, Europe (including the United Kingdom) and Australia, and ProGen will lead development and commercialization 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. For the three and nine months ended September 30, 2025, reimbursement due from ProGen recorded as contra-research and development expense was de minimis.

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 had the 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 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. The Occupancy Services for the facility in Milpitas, California expired in August 2024. The Occupancy Services for the facility in San Antonio, Texas terminated in June 2024.

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 September 30,				Nine Months Ended September 30,			
	2025 2024				2025		2024	
Research and development	\$	180	\$	201	\$	546	\$	768
General and administrative		(11)		41		(38)		187
Total	\$	169	\$	242	\$	508	\$	955

As of September 30, 2025, one of the Company's facilities was owned by an entity affiliated with the Company's Chairman (Note 8). The Company pays for the use of this facility through the RMS-ICL Service Agreement.

Exclusive License 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.

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 nine months ended September 30, 2025 and 2024, these parties to the TRA exchanged zero Paired Interests that resulted in tax benefits subject to the TRA.

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 nine months ended September 30, 2025 and 2024, there were no exchanges of Paired Interest of shares of the Company's Class A common stock between the related parties that are party to the Rani LLC Agreement.

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 terminates 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 had 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. The Company accounted for its Occupancy Services in San Antonio, Texas as a short-term lease. 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 Occupancy Services for 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. The Company accounted for the March 2024 extension for its Occupancy Services in Milpitas, California as a short-term lease. The Occupancy Services for the facility in Milpitas, California expired in August 2024.

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 from the total operating lease expense and are immaterial for the periods presented.

Supplemental information on the Company's condensed consolidated balance sheet and statements of cash flows as of September 30, 2025 and 2024 and for the nine months ended September 30, 2025 and 2024, respectively, related to the Company's leases was as follows (in thousands):

	September 30,				
	202	5	20	24	
Weighted-average remaining lease term (in years)		3.4		4.1	
Weighted-average discount rate		10.4%		10.4%	
		Months End		nber 30,	
Cash flows					
Cash flows Cash paid for amounts included in lease liabilities:					

As of September 30, 2025, minimum annual rental payments under the Company's operating lease agreements are as follows (in thousands), excluding short-term leases:

Year ending December 31,	
2025 (remaining three months)	\$ 475
2026	1,229
2027	1,278
2028	1,330
2029	458
Total undiscounted future minimum lease payments	\$ 4,770
Less: Imputed interest	(753)
Total operating lease liability	\$ 4,017
Less: Current portion of operating lease liability	1,049
Operating lease liability, less current portion	\$ 2,968

9. Warrants

In July 2025, the Company entered into a securities purchase agreement (the "July 2025 Securities Purchase Agreement"), with an institutional investor, relating to the issuance and sale of 4,354,000 shares of Class A common stock, par value \$0.0001 per share, and pre-funded warrants to purchase 3,146,000 shares of Class A common stock. 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 offering price was \$0.40 per share of Class A common stock, and \$0.3999 per pre-funded warrant for total gross proceeds of \$3.0 million. The Company incurred issuance costs of approximately \$0.2 million. Shortly after closing of the offering, the institutional investor fully exercised all pre-funded warrants.

In May 2025, in conjunction with a service agreement, the Company issued warrants to purchase 300,000 shares of the Company's Class A common stock, \$0.0001 par value per share ("Service Warrants") to a third party vendor. The value of the warrants was expensed immediately as a general and administrative cost. The warrants are exercisable for a period of five years from the issuance date, at an exercise price per share equal to \$0.70. The warrants include certain rights upon "fundamental transactions," as described in the warrant agreement, including the right of the holders thereof to receive from the Company 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 of the unexercised portion of the applicable warrants on the date of the consummation of the fundamental transactions. As of September 30, 2025, all of the Service Warrants were outstanding.

In May 2025, the Company entered into a letter agreement (the "Letter Agreement") with an existing institutional investor (the "Equity Investor") pursuant to which the Equity Investor exercised for cash all outstanding Series B and Series C warrants at a reduced exercise price of \$0.65 per share, for net proceeds of \$3.9 million in consideration for the Company's issuance of a new Series D common stock warrant (the "Series D Warrant") to purchase an aggregate of 13,160,172 shares of Class A common stock, \$0.0001 par value per share (the "Class A Common Stock"). Modification accounting was only performed on the warrants that were actually exercised pursuant to the Letter Agreement as it represented a short-term inducement. The Company remeasured the warrants at the reduced exercise price and recognized \$0 and \$1.3 million inducement charge in the unaudited condensed consolidated statements of changes in stockholders' (deficit)/equity for the three months and nine months ended September 30, 2025, respectively.

The Series D Warrants are exercisable immediately following stockholder approval, and will expire five years from the date of stockholder approval and have an exercise price of \$0.65 per share. The Series D Warrants include certain rights upon "fundamental transactions," as described in the Series D Warrant agreement, including the right of the holders thereof to receive from the Company 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 of the unexercised portion of the applicable Series D Warrants on the date of the consummation of the fundamental transactions. As of September 30, 2025, there were 13,160,172 Series D Warrants outstanding.

Pursuant to the terms of the Letter Agreement, in the event that the exercise of the Series B and Series C warrants would have otherwise caused a holder to exceed the beneficial ownership limitations set forth in the existing warrant, the Company issued the number of shares that would not cause a holder to exceed such beneficial ownership limitation and agreed to hold such balance of shares of common stock in abeyance. Accordingly, an aggregate of 1,161,000 shares of common stock were held in abeyance (the "Abeyance Shares") with such Abeyance Shares evidenced through the holder's existing warrants and which are deemed to be prepaid. The Abeyance Shares were to be held until notice is received by the holder that the balance of the shares of common stock may be issued in compliance with such beneficial ownership limitations and may be exercised pursuant to a notice of exercise from the holder. The Abeyance Shares were subsequently released during July 2025.

In October 2024, the Company entered into a securities purchase agreement (the "October Securities Purchase Agreement") with the Equity Investor relating to the issuance and sale of: (i) 3,000,000 shares of its Class A common stock, par value \$0.0001 per share, (ii) pre-funded warrants to purchase 333,333 shares of Class A common stock, and (iii) Series C common warrants, which accompany the Class A common stock and pre-funded warrants, to purchase an aggregate of 3,333,333 shares of Class A common stock (the "October Offering"). Pursuant to the October Securities Purchase Agreement, Series A common warrants to purchase an aggregate of 3,246,753 shares of Class A common stock issued in connection with the July securities purchase agreement were cancelled. The pre-funded warrants were exercisable immediately and had an unlimited term and an exercise price of \$0.0001 per share. The Series C common warrants were exercisable immediately following the closing date and were to expire five years from the date of issuance and originally had an exercise price of \$3.00 per share. The Series C warrants included certain rights upon "fundamental transactions," as described in the Series C warrants, including the right of the holders thereof to receive from the Company 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 of the unexercised portion of the applicable Series C warrants on the date of the consummation of the fundamental transactions. In October 2024, the prefunded warrants were fully exercised for de minimis proceeds. As of September 30, 2025, all Series C warrants had been fully exercised.

In July 2024, the Company entered into a securities purchase agreement (the "July Securities Purchase Agreement") with the Equity Investor relating to the issuance and sale of: (i) 2,800,000 shares of 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 "July Offering"). Pursuant to the October Securities Purchase Agreement, the Series A common warrants to purchase an aggregate of 3,246,753 shares of Class A common stock issued were cancelled. The Series B warrants were exercisable following the six-month anniversary of the closing date and were to expire five and a half years from the date of issuance and had an exercise price of \$3.08 per share. The Series B warrants included certain rights upon "fundamental transactions," as described in the Series B warrants, including the right of the holders thereof to receive from the Company 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 of the unexercised portion of the applicable Series B warrants on the date of the consummation of the fundamental transactions. In August 2024, the pre-funded warrants were fully exercised for de minimis proceeds. As of September 30, 2025, all Series B warrants had been fully exercised.

In August 2022, in conjunction with a loan and security agreement (Note 13), 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. In September 2025, the Company modified the exercise price of the warrants to \$0.50 in consideration for a deferral of a principal repayment due in October 2025. There were no other changes to the terms of the warrant agreement. On the modification date, the Company remeasured the warrants at the reduced exercise price and recognized additional charge of approximately \$15 thousand in the unaudited condensed consolidated statements for the three months and nine months ended September 30, 2025. As of September 30, 2025, there were 76,336 warrants outstanding.

Warrant activity

A summary of warrant activity during the periods indicated is as follows:

	Number of Warrants	Veighted age Exercise Price	Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)	
Outstanding at December 31, 2024 [†]	6,656,422	\$ 3.10	4.66	\$	_
Granted	13,460,172	\$ 0.65	4.99	\$	_
Exercised*	(6,580,086)	\$ 0.65			
Outstanding at September 30, 2025	13,536,508	\$ 0.65	4.72	\$	38

 $\dot{\tau}$ Included in the December 31, 2024 balance are 76,336 warrants with an exercise price of \$11.79 per share, which were modified in the three and nine months ended September 30, 2025 to subsequently have an exercise price of \$0.50 per share.

* Note that these warrants had an initial exercise price of \$3.00 per share and were modified in May 2025 to a new exercise price of \$0.65 per share.

10. Stockholders' Equity

As of September 30, 2025, Rani Holdings held approximately 66% of the Class A Units of Rani LLC, and approximately 34% of the outstanding Class A Units of Rani LLC are held by the Continuing LLC Owners. From the date of the Organizational Transactions to September 30, 2025, 5,378,539 Paired Interests and 362,821 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 nine months ended September 30, 2025 and 2024, certain of the Continuing LLC Owners executed an exchange of zero Paired Interests and zero and 83,377 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 accordance with the Rani LLC Agreement, Rani LLC also issues a corresponding Class A Unit to Rani Holdings for each share of common stock issued by Rani Holdings. This increases Rani Holdings' ownership in Rani LLC.

11. Stock-Based Compensation

Stock Options

A summary of stock option activity during the periods indicated is as follows:

	Number of Stock Option Awards	eighted age Exercise Price	Weighted Average Remaining Contractual Term (in years)	Int	Aggregate rinsic Value thousands)
Outstanding at December 31, 2024	10,225,433	\$ 5.52	8.18	\$	
Granted	4,273,930	\$ 0.82	9.61	\$	_
Canceled	(1,632,284)	\$ 4.81			
Outstanding at September 30, 2025	12,867,079	\$ 4.05	8.11	\$	_
Exercisable at September 30, 2025	6,396,853	\$ 6.21	7.20	\$	_
Nonvested at September 30, 2025	6,470,226	\$ 1.92	9.01		

As of September 30, 2025, there was \$8.4 million of unrecognized stock-based compensation expense related to stock options which is expected to be recognized over a weighted-average period of approximately 2.6 years.

The Company uses the Black-Scholes option pricing model to estimate the fair value of each stock option award on the date of grant. The assumptions and estimates are as follows:

- Expected term The expected term represents the period of time that stock option awards are expected to remain
 outstanding. The Company estimates the expected term as the midpoint between actual or expected vesting date and
 the contractual term.
- Expected volatility The expected volatility was derived from the historical stock volatilities of peer public
 companies within the Company's industry that are considered to be comparable businesses over a period equivalent
 to the expected term of the stock option awards, since there has been limited trading history of the Company's stock.
- Risk-free interest rate The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of
 grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the stock option awards' expected
 term.
- Expected dividend yield The expected dividend yield is zero as the Company has no plans to make dividend payments.

The following table sets forth the weighted average assumptions used in estimating the fair value of stock option awards on the grant date:

	September 30,
	2025
Expected volatility	91.9 %
Risk-free interest rate	4.15 %
Expected term (in years)	5.9
Expected dividend yield	— %

Restricted Stock Units

A summary of restricted stock unit ("RSU") activity during the periods indicated is as follows:

	Number of Restricted Stock Units	Weighted Average Gran Date Fair Value per Shai	
Unvested balance at December 31, 2024	811,893	\$ 7.0)8
Vested	(273,546)	\$ 7.8	38
Forfeited	(122,042)	\$ 6.4	14
Unvested balance at September 30, 2025	416,305	\$ 6.7	75

As of September 30, 2025, there was \$2.0 million of unrecognized stock-based compensation expense related to RSUs which is expected to be recognized over a weighted-average period of approximately 1.3 years. The total fair value of RSUs vested was \$0.1 million for the nine months ended September 30, 2025.

Stock-Based Compensation Expense

The following table summarizes the components of stock-based compensation expense resulting from the grant of stock options, RSUs, RSAs, and the ESPP, recorded in the Company's condensed consolidated statement of operations (in thousands):

	Nine Months Ended September 30,			
		2025		2024
Research and development	\$	3,086	\$	3,563
General and administrative		6,474		8,477
Total stock-based compensation	\$	9,560	\$	12,040

12. 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 September 30, 2025, 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 \$23.4 million at September 30, 2025.

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.

13. Long-Term Debt

In August 2022, the Company entered into a loan and security agreement and related supplement (the "Loan Agreement") with Avenue Venture Opportunities Fund, L.P (the "Lender"). The Loan Agreement provides for term loans (the "Loans") in an aggregate principal amount up to \$45.0 million. A Loan of \$30.0 million was committed at closing, with \$15.0 million funded immediately and \$15.0 million available to be drawn between October 1, 2022 and December 31, 2022, which was drawn in December 2022. The remaining \$15.0 million of Loans was uncommitted and subject to certain conditions and is no longer available under the Loan Agreement. 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 Loan principal is repayable in equal monthly installments beginning September 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 include 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 September 30, 2025, the effective interest rate on the Loans was 14.60% and there were no events of default during the nine months ended September 30, 2025. 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 September 30, 2025, the Company was in compliance with all applicable financial covenants under the Loan Agreement.

As of September 30, 2025, future principal payments for the Company's debt are as follows (in thousands):

Year ending December 31,	
2025 (remaining three months)	\$ 3,750
2026	10,000
Total principal payments	\$ 13,750
Less: amount representing debt discount	(213)
Total long-term debt	\$ 13,537
Less: current portion of long-term debt	13,537
Total long-term debt, less current portion	\$

In October 2025, concurrently with the Company's Private Placement financing, the Lender converted \$6.0 million of the Loans into equity on the same terms as other investors in the Private Placement. Refer to the subsequent event in Note 16.

14. Income Taxes

The Company's effective income tax rate was zero for each of the nine months ended September 30, 2025 and 2024. As a result 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 nine months ended September 30, 2025 and 2024, and the Company does not anticipate material changes within the next twelve months.

Recent Legislation

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law, which enacts significant changes to U.S. tax and related laws. Some of the provisions of the new tax law affecting corporations include but are not limited to current deduction of domestic research expenses, increasing the limit of the deduction of interest expense deduction to thirty percent of EBITDA, and one hundred percent bonus depreciation on eligible property acquired after January 19, 2025. The OBBBA has varying effective dates, with certain provisions effective in 2025 and others with multiple effective dates through 2027. We have evaluated the potential impact of this legislation and expect it to result primarily in a timing difference, with no material impact on our effective tax rate.

15. Net Loss Per Share

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

	Three Months Ended September 30,		Nin	e Months Ended	September	
		2025	2024		2025	2024
Numerator:						
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.	\$	(5,412)\$	(6,783)	\$	(19,368)\$	(21,071)
Denominator:						
Weighted average Class A common share						
outstanding—basic and diluted		46,444	28,836		38,856	27,071
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.—basic and diluted	\$	(0.12)\$	(0.24)	\$	(0.50)\$	(0.78)

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 Septe	mber 30,
	2025	2024
Paired Interests	23,970	24,116
Stock options	12,867	10,296
Warrants	13,537	6,570
Non-corresponding Class A Units	1,124	1,262
Restricted stock units	416	893
Shares issuable pursuant to the ESPP	56	41
Restricted stock awards	_	11
	51,970	43,189

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 nine months ended September 30, 2025. Therefore, they are not included in the computation of net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.

16. Subsequent Events

Collaboration and License Agreement

In October 2025, the Company and Chugai Pharmaceutical Co., Ltd. ("Chugai") entered into a Collaboration and License Agreement (the "Collaboration and License Agreement"). Under the Collaboration and License Agreement, the Company and Chugai will collaborate to develop, manufacture, seek regulatory approvals for and, if approved, commercialize a product (the "Product") combining Chugai's antibody (the "Compound"), which is in development for hemophilia, and the RaniPill HC oral delivery device

(the "Device") for use in humans. Under the Collaboration and License Agreement, the Company is entitled to receive a \$10.0 million upfront payment within 30 days of Chugai receiving an invoice for the upfront payment after closing. The Company is eligible to receive up to \$18.0 million in technology transfer milestones, up to \$57.0 million in development milestones, up to \$100.0 million in a series of sales-based milestones, contingent upon approval and the commercial success of the product, and single digit royalties on net sales upon approval and successful commercialization of the Product.

Private Placement

In October 2025, the Company entered into a securities purchase agreement with (i) certain institutional and accredited investors (the "Institutional Investors") and (ii) Mir Imran, chairman of the Company's Board of Directors (the "Affiliated Investor" and, together with the Institutional Investors, each, a "Purchaser" and, together, the "Purchasers"), pursuant to which the Company issued and sold in a private placement (the "Private Placement") (i) 42,633,337 shares (the "Shares") of its Class A common stock, par value \$0.0001 per share (the "Class A Common Stock"), (ii) warrants to purchase up to an aggregate of 125,000,004 shares of Class A Common Stock or prefunded warrants (the "Common Warrants") and (iii) pre-funded warrants to purchase up to an aggregate of 82,366,667 shares of Class A Common Stock (the "Pre-Funded Warrants"). The purchase price of the Shares to the Institutional Investors is \$0.48 per share; and the purchase price of the Shares to the Affiliated Investor is \$0.605 per share. The purchase price of the Pre-Funded Warrants to the Purchasers is \$0.4799 per Pre-Funded Warrant. The aggregate gross proceeds to the Company from the closing of the Private Placement are approximately \$60.3 million (including conversion of the Loan amount of \$6.0 million), before deducting placement agent fees of approximately \$3.0 million and other expenses payable by the Company, and excluding the proceeds, if any, from the exercise of the Common Warrants.

The Common Warrants will become exercisable following the effective date of stockholder approval and have a term of five years following the initial exercise date. The Common Warrants purchased by the Purchasers have an exercise price of \$0.48 per share. The Pre-Funded Warrants are exercisable immediately following the closing, have an unlimited term and an exercise price of \$0.0001 per share. The Company also agreed to seek approval from its stockholders for the issuance of the shares issuable upon exercise of the Common Warrants within 75 days following the closing date of the Private Placement.

The Company's chairman of the Board of Directors participated in the Private Placement and purchased 2,083,334 Shares and 2,083,334 Common Warrants for the aggregate purchase price of \$1.3 million.

Registration Rights Agreement

In October 2025, the Company entered into a registration rights agreement with the Purchasers (the "Registration Rights Agreement"), pursuant to which the Company agreed to file registration statements under the Securities Act of 1933, as amended (the "Securities Act"), with the Securities and Exchange Commission, covering the resale of the Shares to be issued in the Private Placement and the shares of Class A Common Stock underlying the Common Warrants and Pre-Funded Warrants no later than 15 days following the Closing date, and to use reasonable best efforts to have the registration statement declared effective 45 days after the Closing date, and in any event no later than 90 days following the Closing date in the event of a "full review" by the SEC.

Debt Conversion

In October 2025, the Company and the Lender entered into an amendment to the Loan Agreement (the "LSA Amendment"), pursuant to which the Lender agreed, among other things, to convert \$6.0 million of outstanding Loans into 12,500,000 Shares (or Pre-Funded Warrants in lieu thereof) in connection with the Private Placement and receive warrants to purchase up to 12,500,000 shares of Class A Common Stock (or Pre-Funded Warrants in lieu thereof), on the same terms as the Purchasers. Refer to Note 13 for the Loan Agreement previously entered.

Series D Warrant Exercises

In October 2025, pursuant to the Letter Agreement entered in May 2025 (Note 9), the Equity Investor exercised the Series D Warrants to purchase 6,967,150 shares of Class A Common Stock for the aggregate exercise price of \$4.5 million. As a result of the exercise, 6,193,022 Series D Warrants remained outstanding. The Company received cash proceeds of \$4.5 million as a result of the exercise.

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, 2024, as filed with the Securities and Exchange Commission ("SEC"). Some of the information contained in this discussion and analysis or set forth elsewhere in this document, includes forward looking statements that involve risks, uncertainties, and assumptions. Our actual results could differ materially from those discussed in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors" in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2024. Please also see the section titled "Forward Looking Statements."

The following discussion contains references to calendar year 2024 and the three and nine months ended September 30, 2025 and 2024, 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, 2024 and the three and nine months ended September 30, 2025 and 2024, 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 have 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 $200\mu L$ 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 by the end of 2025.

We believe the RaniPill capsule technology 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 RaniPill capsule. 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 RaniPill capsule. 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 RaniPill

capsule. 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.

Financial Update

In May 2025, we entered into a letter agreement (the "Letter Agreement") with an existing institutional investor (the "Equity Investor") pursuant to which the Equity Investor exercised for cash all outstanding Series B and Series C warrants held by such Equity Investor at a reduced exercise price of \$0.65 per share, for net proceeds of \$3.9 million, in consideration for the issuance of a new Series D common stock warrant (the "Series D Warrant") to purchase an aggregate of 13,160,172 shares of Class A common stock, \$0.0001 par value per share (the "Class A Common Stock").

In July 2025, we entered into the July 2025 Securities Purchase Agreement with an institutional investor, relating to the issuance and sale of 4,354,000 shares of Class A common stock, par value \$0.0001 per share, and pre-funded warrants to purchase 3,146,000 shares of Class A common stock (the "Offering"). The pre-funded warrants were exercisable immediately following the closing date of the Offering and have an unlimited term and an exercise price of \$0.0001 per share. The Offering price was \$0.40 per share of Class A common stock, and \$0.3999 per pre-funded warrant for total gross proceeds of \$3.0 million. After the closing the Offering, the institutional investor fully exercised all pre-funded warrants.

As of September 30, 2025, our cash, cash equivalents, and restricted cash equivalents totaled \$4.6 million. In October 2025, we entered into a securities purchase agreement pursuant to which we sold in the Private Placement (i) 42,633,337 shares of our Class A Common Stock, (ii) warrants to purchase up to an aggregate of 125,000,004 shares of Class A Common Stock or pre-funded warrants (the "Common Warrants"), and (iii) pre-funded warrants to purchase up to an aggregate of 82,366,667 shares of Class A Common Stock (the "Pre-Funded Warrants") for the aggregate purchase price of approximately \$60.3 million (including conversion of the Loan amount of \$6.0 million described below).

The Common Warrants will become exercisable following the effective date of stockholder approval and have a term of five years following the initial exercise date. The Common Warrants have an exercise price of \$0.48 per share. The Pre-Funded Warrants are exercisable immediately, have an unlimited term and an exercise price of \$0.0001 per share. We also agreed to seek approval from our stockholders for the issuance of the shares issuable upon exercise of the Common Warrants within 75 days following the closing date of the Private Placement.

In October 2025, we entered into the LSA Amendment with the Lender, pursuant to which the Lender, among other things, converted \$6.0 million of outstanding Loans into 12,500,000 shares of our Class A Common Stock (or Pre-Funded Warrants in lieu thereof) and Common Warrants to purchase up to 12,500,000 shares of Class A Common Stock (or Pre-Funded Warrants in lieu thereof), on the same terms as other investors in the Private Placement.

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. 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, strategic transactions or other arrangements with other companies, or through other sources of financing. The sale of additional equity would result in additional dilution to our stockholders. The incurrence of additional debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations. We may not be able to raise additional financing on terms acceptable to us or at all. If we are unable to raise additional capital when desired, our business, operating results, and financial condition could be adversely affected.

Preclinical Update

In May 2025, we announced that we have entered a Research Collaboration in August 2024 for two molecules with undisclosed targets provided by Chugai Pharmaceutical Co., Ltd. The full analysis confirms the RaniPill® delivery demonstrated comparable bioavailability to the subcutaneous route of delivery for both molecules studied.

In March 2025, we announced preclinical data demonstrating bioequivalence of RT-114, a bispecific GLP-1/GLP-2 receptor agonist (PG-102) delivered orally via the RaniPill capsule ("RT-114"), to subcutaneously administered PG-102. RT-114 yielded a relative bioavailability of 111% compared to PG-102 delivered subcutaneously with comparable pharmacokinetic profiles and weight loss. RT-114 was well tolerated and was excreted without sequelae in all subjects. Average peak weight loss was the same in both groups with greater variability with subcutaneous dosing $(6.7\% \pm 0.5\%$ for RT-114 and $6.7\% \pm 2.2\%$ for subcutaneous PG-102). In July 2025, the same set of data was presented at the ENDO conference in San Francisco, California. Collectively, these compelling nonclinical results provide a robust rationale for initiating clinical development of RT-114 as a first-in-class oral antiobesity therapy. We plan to initiate a Phase 1 trial for RT-114 by the end of 2025. The upcoming trial will evaluate safety, tolerability, and pharmacokinetics, laying the groundwork for future development phases.

In February 2025, we announced preclinical data demonstrating successful oral delivery of the glucagon-like peptide-1 receptor ("GLP-1") agonist semaglutide via the RaniPill HC ("RT-116"). In the study, RT-116 demonstrated comparable bioavailability, pharmacokinetics and weight loss to subcutaneous ("SC") administration of semaglutide. Further, RT-116 was well tolerated with no serious adverse events.

Collaboration and License Agreement

In October 2025, we entered into the Collaboration and License Agreement with Chugai to develop, manufacture, seek regulatory approvals for and, if approved, commercialize the Product combining Chugai's Compound, which is in development for hemophilia, and the Device for use in humans. Under the Collaboration and License Agreement, we are entitled to receive a \$10.0 million upfront payment within 30 days of Chugai receiving an invoice for the upfront payment after closing. We would be eligible to receive up to \$18.0 million in technology transfer milestones, up to \$57.0 million in development milestones, up to \$100.0 million in a series of sales-based milestones, contingent upon approval and the commercial success of the product, and single digit royalties on net sales upon approval and successful commercialization of the Product.

In accordance with a development plan, the parties will share responsibility for the development of the Product worldwide, with Chugai leading and having sole responsibility for clinical, regulatory, and commercial activities. The parties will allocate preclinical, Chemistry Manufacturing and Controls, and manufacturing and supply activities between each other, with Chugai being primarily responsible for development of the Compound and us being primarily responsible for development of the Device and Product

Under the Collaboration and License Agreement, the Company granted Chugai an exclusive, worldwide right and license to certain intellectual property owned by us to research, develop, register, manufacture, use, sell, offer to sell, import, export, commercialize, and market the Product. Chugai granted us a non-exclusive, worldwide right and license to certain intellectual property owned by Chugai to manufacture and supply the Device and Product to Chugai and to perform its activities under the Collaboration and License Agreement. Both parties have the right to sublicense subject to certain conditions.

In addition, Chugai has a one-time limited option to replace the Compound with a different compound subject to certain terms and conditions, a time-limited right of first refusal with respect to a select group of additional targets, and a time-limited option to extend its rights to up to five of the additional drug targets under similar deal terms as the Collaboration and License Agreement.

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-O 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 September 30, 2025 and 2024

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

	Three Months Ended September 30,				
		2025		2024	Change
Operating expenses					
Research and development		3,221		6,172	(47.8)%
General and administrative		4,036		5,627	(28.3)%
Total operating expenses	\$	7,257	\$	11,799	(38.5)%
Loss from operations		(7,257)		(11,799)	(38.5)%
Other income (expense), net					
Interest income and other, net		68		414	(83.6)%
Interest expense and other, net		(725)		(1,337)	(45.8)%
Net loss	\$	(7,914)	\$	(12,722)	(37.8)%
Net loss attributable to non-controlling interest		(2,502)		(5,939)	(57.9)%
Net loss attributable to Rani Therapeutics Holdings, Inc.	\$	(5,412)	\$	(6,783)	(20.2)%

Research and Development Expenses

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

	Three Months 1	Three Months Ended September 30,			
	2025		2024		
Payroll, stock-based compensation and related benefits	\$ 2,245	\$	4,623		
Facilities, materials and supplies	950	,	1,357		
Third-party services	18	3	173		
Other	2	2	19		
Total	\$ 3,22	\$	6,172		

The decrease of \$3.0 million in research and development expenses in the three months ended September 30, 2025, as compared to the same period in 2024, was primarily attributed a \$2.4 million reduction in compensation costs resulting from lower headcount, a \$0.4 million decrease in expenses related to facilities, materials and supplies, and a \$0.2 million decrease in third-party services. These reductions reflect cost containment efforts, including the temporary pause of certain R&D programs. We anticipate the R&D expenses to increase in future periods as we resume these programs and continue to invest in product development.

General and Administrative Expenses

The decrease of \$1.6 million in general and administrative expenses in the three months ended September 30, 2025, as compared to the same period in 2024, was primarily attributed to lower compensation costs of \$1.3 million and a reduction of \$0.3 million in third-party services.

Other Income (Expense), Net

The decrease of \$0.3 million in other income (expense), net, in the three months ended September 30, 2025, as compared to the same period in 2024, was primarily attributed to a decrease in interest income of \$0.3 million from our investments, offset by a decrease in interest expenses of \$0.6 million.

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

	Nine Months Ended September 30,				
		2025		2024	Change
Contract revenue	\$	172	\$	_	* %
Operating expenses					
Research and development		15,296		19,872	(23.0)%
General and administrative		14,651		18,484	(20.7)%
Total operating expenses	\$	29,947	\$	38,356	(21.9)%
Loss from operations		(29,775)		(38,356)	(22.4)%
Other income (expense), net					
Interest income and other, net		443		1,403	(68.4)%
Interest expense and other, net		(2,544)		(3,909)	(34.9)%
Net loss	\$	(31,876)	\$	(40,862)	(22.0)%
Net loss attributable to non-controlling interest		(12,508)		(19,791)	(36.8)%
Net loss attributable to Rani Therapeutics Holdings, Inc.	\$	(19,368)	\$	(21,071)	(8.1)%

^{*} Not meaningful

Contract Revenue

Contract revenue of \$0.2 million for the nine months ended September 30, 2025, was attributable to evaluation services performed for the evaluation agreement with Chugai. There was no contract revenue for the same period in 2024.

Research and Development Expenses

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

	Nii	Nine Months Ended September 30,			
		2025		2024	
Payroll, stock-based compensation and related benefits	\$	10,937	\$	15,048	
Facilities, materials and supplies		3,609		3,957	
Third-party services		731		820	
Other		19		47	
Total	\$	15,296	\$	19,872	

The decrease of \$4.6 million in research and development expenses in the nine months ended September 30, 2025, as compared to the same period in 2024, was primarily attributed to a \$4.1 million reduction in compensation costs resulting from lower headcount, a \$0.4 million of reduced spending on material and supplies, and a \$0.1 million decrease in third-party services.

General and Administrative Expenses

The decrease of \$3.8 million in general and administrative expenses in the nine months ended September 30, 2025, as compared to the same period in 2024, was primarily attributed to lower compensation costs of \$2.3 million, \$1.4 million reduction in third-party services, and \$0.1 million reduction in other expenses.

Other Income (Expense), Net

The decrease of \$0.4 million in other income (expense), net, in the nine months ended September 30, 2025, as compared to the same period in 2024, was primarily attributed to a decrease in interest income of \$1.0 million from our investments, offset by a decrease in interest expenses of \$1.4 million.

Liquidity and Capital Resources

Overview

We have incurred recurring losses and negative cash flows from operations since inception, including net loss of \$31.9 million for nine months ended September 30, 2025. As of September 30, 2025, we had an accumulated deficit of \$122.3 million and for nine months ended September 30, 2025, had negative cash flows from operations of \$19.0 million. As of September 30, 2025, our cash, cash equivalents, and restricted cash equivalents totaled \$4.6 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.

As disclosed in more detail below, we have entered into various financing agreements and a license and collaboration agreement in October 2025. We believe that the proceeds from the closing of the Private Placement, the upfront payment from the Collaboration and License Agreement with Chugai, the proceeds received from Series D Warrant exercises, and the impact of the Debt Conversion provide sufficient capital resources to meet our operating obligations for at least twelve months from the date the condensed consolidated financial statements are issued. Our management believes that the going concern doubt in our 2024 10-K and previous quarterly reports on Form 10-Q has been alleviated.

Financial Update

In October 2025, we entered into a securities purchase agreement pursuant to which we sold in the Private Placement (i) 42,633,337 shares of our Class A Common Stock, (ii) warrants to purchase up to an aggregate of 125,000,004 shares of Class A Common Stock or pre-funded warrants (the "Common Warrants") and (iii) pre-funded warrants to purchase up to an aggregate of 82,366,667 shares of Class A Common Stock (the "Pre-Funded Warrants"), for the aggregate purchase price of approximately \$60.3 million (including conversion of the Loan amount of \$6.0 million described below).

The Common Warrants will become exercisable following the effective date of stockholder approval and have a term of five years following the initial exercise date. The Common Warrants have an exercise price of \$0.48 per share. The Pre-Funded Warrants are exercisable immediately, have an unlimited term and an exercise price of \$0.0001 per share. We also agreed to seek approval from our stockholders for the issuance of the shares issuable upon exercise of the Common Warrants within 75 days following the closing date of the Private Placement

In October 2025, we entered into the LSA Amendment with the Lender, pursuant to which the Lender, among other things, converted \$6.0 million of outstanding Loans into 12,500,000 shares of our Class A Common Stock (or Pre-Funded Warrants in lieu thereof) and Common Warrants to purchase up to 12,500,000 shares of Class A Common Stock (or Pre-Funded Warrants in lieu thereof), on the same terms as other investors in the Private Placement.

In October 2025, we entered into the Collaboration and License Agreement with Chugai to develop, manufacture, seek regulatory approvals for and, if approved, commercialize the Product combining Chugai's Compound, which is in development for hemophilia, and the Device for use in humans. Under the Collaboration and License Agreement, the Company will receive a \$10.0 million upfront payment within 30 days of Chugai receiving an invoice for the upfront payment after closing. We are eligible to receive up to \$18.0 million in technology transfer milestones, up to \$57.0 million in development milestones, up to \$100.0 million in a series of sales-based milestones, contingent upon approval and the commercial success of the product, and single digit royalties on net sales, contingent on approval and commercialization of the Product.

In July 2025, we entered into the July Securities Purchase Agreement with an institutional investor, relating to the issuance and sale of 4,354,000 shares of Class A common stock, par value \$0.0001 per share, and pre-funded warrants to purchase 3,146,000 shares of Class A common stock. 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 Offering price was \$0.40 per share of Class A common stock and \$0.3999 per pre-funded warrant for total gross proceeds of \$3.0 million. After closing of the Offering, the institutional investor fully exercised all pre-funded warrants.

In May 2025, we entered into the Letter Agreement with an existing institutional investor (the "Equity Investor") pursuant to which the Investor exercised for cash all outstanding Series B and Series C warrants at a reduced exercise price of \$0.65 per share in consideration for the Company's issuance of a the Series D Warrant to purchase an aggregate of 13,160,172 shares of Class A common stock, \$0.0001 par value per share with the exercise price of \$0.65 per share. In October 2025, the Equity Investor exercised 6,967,150 shares of Series D Warrants, resulting in 6,193,022 shares of Series D Warrants remained outstanding. The Company received cash proceeds of \$4.5 million as a result of the exercise.

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 was uncommitted and subject to certain conditions and is no longer available under the Loan Agreement. The Loan Agreement also contains various covenants and restrictive provisions. There have been no material adverse events in connection with the Loan Agreement. The Loan principal is repayable in equal monthly installments which began in September 2024. As of September 30, 2025, we were in compliance with all financial covenants under the Loan Agreement.

Tax Receivable Agreement

See Note 12 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

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 technology 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 technology and our product candidates.

We may seek to raise capital through equity offerings or debt financings, which may include 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 technology 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.

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.

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

	ember 30, 2025	December 31, 2024		
Cash and cash equivalents	\$ 4,144	\$	3,762	
Marketable securities	_		23,877	
Total cash, cash equivalents and marketable securities	\$ 4,144	\$	27,639	

As of September 30, 2025, we had cash and cash equivalents and marketable securities of \$4.1 million, compared to \$27.6 million as of December 31, 2024.

Cash Flows

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

	Nine Months Ended September 30,					
	2025			2024		
Net cash used in operating activities	\$	(19,008)	\$	(26,841)		
Net cash provided by investing activities		23,942		17,288		
Net cash (used in)/provided by financing activities		(4,552)		7,966		
Net increase/(decrease) in cash, cash equivalents and restricted cash						
equivalents	\$	382	\$	(1,587)		

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2025 was \$19.0 million, which was primarily attributable to a net loss of \$31.9 million and net accretion and amortization of investments in marketable securities of \$0.2 million, partially offset by stock-based compensation expense of \$9.6 million, depreciation and amortization expense of \$0.7 million and \$0.2 million in warrant issuance costs and expenses. Additionally, there was an increase in accounts payable of \$1.1 million, accrued expenses and other current liabilities of \$0.6 million and a decrease in contract asset of \$0.4 million and prepaid expenses and other current assets of \$0.9 million for the nine months ended September 30, 2025.

Net cash used in operating activities for the nine months ended September 30, 2024 was \$26.8 million, which was primarily attributable to a net loss of \$40.9 million and net accretion and amortization of investments in marketable securities of \$0.9 million, partially offset by stock-based compensation expense of \$12.0 million and depreciation and amortization expense of \$0.8 million. Additionally, there was an increase in accounts payable of \$0.9 million, an increase in deferred revenue of \$0.6 million and an increase of \$0.3 million in prepaid expenses and other current assets for the nine months ended September 30, 2024.

Investing Activities

For the nine months ended September 30, 2025, net cash provided by investing activities was \$23.9 million, which primarily consisted of \$26.8 million in proceeds from maturities of marketable securities partially offset by \$2.7 million in purchases of marketable securities and \$0.1 million in purchases of property and equipment.

For the nine months ended September 30, 2024, net cash provided by investing activities was \$17.3 million, which primarily consisted of \$57.3 million in proceeds from maturities of marketable securities partially offset by \$39.7 million in purchases of marketable securities and \$0.2 million in purchases of property and equipment.

Financing Activities

For the nine months ended September 30, 2025, net cash used in financing activities was \$4.6 million, which primarily consisted of repayment of debt of \$11.3 million offset by the exercise of warrants of \$3.9 million, and the issuance of common stock and pre-funded warrants of \$2.8 million.

For the nine months ended September 30, 2024, net cash provided by financing activities was \$8.0 million, which primarily consisted of net proceeds of \$8.9 million from the July Offering and \$0.2 million from the issuance of common stock under the employee stock purchase plan, partially offset by \$1.3 million repayment of debt.

Contractual Obligations and Other Commitments

In October 2025, we entered into the LSA Amendment with the Lender, pursuant to which the Lender, among other things, converted \$6.0 million of outstanding Loans into 12,500,000 shares of our Class A Common Stock (or Pre-Funded Warrants in lieu thereof) and Common Warrants to purchase up to 12,500,000 shares of Class A Common Stock (or Pre-Funded Warrants in lieu thereof), on the same terms as the purchasers in the Private Placement (see Note 16 to our unaudited condensed consolidated financial statements included elsewhere in Part I, Item 1 of this Quarterly Report).

In October 2025, we entered into the Collaboration and License Agreement with Chugai to develop, manufacture, seek regulatory approvals for and, if approved, commercialize the Product combining Chugai's Compound, which is in development for hemophilia, and the Device for use in humans. Under the Collaboration and License Agreement, we are entitled to receive \$10.0 million upfront within 30 days of Chugai receiving an invoice for the upfront payment after closing. We are eligible to receive up to \$18.0 million in technology transfer milestones, up to \$57.0 million in development milestones, up to \$100.0 million in a series of sales-based milestones, contingent upon approval and the commercial success of the product, and single digit royalties on net sales, contingent on approval and commercialization of the Product (see Note 16 to our unaudited condensed consolidated financial statements included elsewhere in Part I, Item 1 of this Quarterly Report).

Other than those described above, management believes that 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 Estimates

We prepare our condensed consolidated financial statements in accordance with U.S. generally accepted accounting principles, which require our management to make estimates that affect the reported amounts of assets, liabilities and disclosures of contingent assets and liabilities at the balance sheet dates, as well as the reported amounts of revenues and expenses during the reporting periods. We base our estimates on our own historical experience and other assumptions that we believe are reasonable after taking account of our circumstances and expectations for the future based on available information. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations would be affected.

We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. There are items within our condensed consolidated financial statements that require estimation but are not deemed critical, as defined above.

Recently Adopted Accounting Standards

None.

Other Information

JOBS Act Accounting Election

We are an "emerging growth company" within the meaning of the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). The JOBS Act permits an emerging growth company like us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are electing to use this extended transition period and we will therefore comply with new or revised accounting standards on the earlier of (i) when they apply to private companies; or (ii) when we lose our emerging growth company status. As a result, our financial statements may not be comparable with companies that comply with public company effective dates for accounting standards. We also rely on other exemptions provided by the JOBS Act, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act unless we cease to be an emerging growth company.

We will remain an emerging growth company until the earliest of (1) December 31, 2026 (the last day of the fiscal year following the fifth anniversary of the closing of our 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 September 30, 2025.

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 September 30, 2025 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 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, 2024.

Our collaboration with Chugai may not be successful, and we may not realize the anticipated benefits of the Collaboration and License Agreement.

In October 2025, we entered into the Collaboration and License Agreement with Chugai to develop, manufacture, seek regulatory approvals for and, if approved, commercialize the Product combining Chugai's Compound, which is in development for hemophilia, and the Device for use in humans. Under the Collaboration and License Agreement, we are entitled to receive an upfront payment of \$10.0 million within 30 days of Chugai receiving an invoice for the upfront payment after closing. We are eligible to receive up to \$18.0 million in technology transfer milestones, up to \$57.0 million in development milestones, up to \$100.0 million in sales-based milestones, contingent upon approval and the commercial success of the product, and single-digit royalties on net sales, contingent on approval and commercialization of the Product. The success of this collaboration is subject to numerous risks and uncertainties, many of which are outside of our control.

Our ability to receive milestone or royalty payments depends on the achievement of specified technology transfer, development, regulatory, and commercial events, many of which depend on both parties' efforts and on the ultimate performance, approval and commercialization of the Product including the Compound and the Device. As a result, we may not receive any or all of the potential milestone or royalty payments contemplated by the Agreement.

Chugai has primary responsibility for preclinical and clinical development, regulatory filings, and commercialization of the Product, while we are responsible for development of the device and for certain manufacturing and supply activities. If Chugai fails to devote sufficient resources to the collaboration or otherwise determines to reprioritize or discontinue development of the Product, our ability to advance the program would be materially and adversely affected. Moreover, the development of the Product is significant scientific, regulatory, and commercial risks inherent in drug and combination product development. There can be no assurance that the Product will successfully complete preclinical or clinical studies, obtain regulatory approval, or achieve commercial success, if approved.

In addition, Chugai holds certain options and rights under the Agreement, including a one-time right to replace the compound, a right of first refusal for certain additional drug targets, and options to extend its rights to additional drug targets. The exercise of these rights could alter the scope or economics of the collaboration, or may not occur at all, which could affect the potential value of the arrangement to us. If the collaboration is significantly delayed or terminates early, whether due to breach, convenience, or other circumstances, we may be unable to continue development of the Product. Any of these events could materially harm our business, financial condition, and results of operations.

We have in the past and may in the future fail to continue to meet the listing standards of Nasdaq, and as a result our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock.

Our Class A common stock is currently listed on The Nasdaq Global Market. We are required to meet specified requirements to maintain our listing on The Nasdaq Global Market, including, among others, a minimum bid price of \$1.00 per share of our class A common stock under Nasdaq Listing Rule 5450(a)(1) ("Minimum Bid Price Requirement") and a minimum market value of listed securities ("MVLS"), of \$50,000,000 under Nasdaq Listing Rule 5450(b)(2)(A) (the "MVLS Requirement").

On June 20, 2025, we received a letter from the Listing Qualifications Staff of Nasdaq ("Nasdaq Staff") notifying us that for the last 30 consecutive business days, the bid price of our common stock had closed below \$1.00 per share, and was not in compliance with the Minimum Bid Price Requirement. The notification received had no immediate effect on the listing of our

common stock on the Nasdaq. In accordance with Nasdaq Listing Rules, we had 180 calendar days to regain compliance with the minimum bid price requirement by having shares of our common stock maintain a minimum closing bid price of at least \$1.00 per share for a minimum of 10 consecutive business days.

On May 1, 2025, we received a letter from the Nasdaq Staff notifying us that we were not in compliance with the MVLS Requirement (the "MVLS Notice"). The notification received had no immediate effect on the listing of our common stock on the Nasdaq. In accordance with the Nasdaq Listing Rules, we were granted 180 calendar days to regain compliance with the MVLS Requirement. In order to do so, we must achieve and maintain an MVLS of at least \$50,000,000 or more for a minimum of 10 consecutive business days.

On November 4, 2025, we received two letters from the Nasdaq Staff. The first letter from the Nasdaq Staff indicated that the closing bid price of our Class A common stock had been at \$1.00 per share or greater for the last 10 consecutive business days, from October 21, 2025, to November 3, 2025, and accordingly, we have regained compliance with Nasdaq Listing Rules 5450(a)(1). The second letter from the Nasdaq Staff indicated that the MVLS of our Class A common stock had been at a value of at least \$50,000,000 for the last 10 consecutive business days, from October 17, 2025, to October 30, 2025, and accordingly, we had regained compliance with Nasdaq Listing Rules 5450(b)(2)(A). There can be no assurance that we will continue to meet the Minimum Bid Price Requirement, MVLS requirement, or any other Nasdaq requirements in the future.

In addition, we may be unable to meet other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders' equity or market values of our common stock, in which case our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected, and the market price of our common stock could decrease.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States, including suppliers of drug substance for our pipeline programs and suppliers of certain raw materials for the manufacture of the RaniPill® capsule. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

We manufacture the RaniPill® capsule in the United States. We are vertically integrated and manufacture many of the components used in the RaniPill® capsule. We source raw materials for our components and manufacturing from a variety of suppliers. Currently, nearly all of the principal suppliers of our raw materials and externally-sourced components used to support our manufacturing come from suppliers located in the United States. The current principal supplier of one raw material is located in China. We obtain supply of the drug substances used for our pipeline programs from third parties. The drug substance for our RT-114 (bispecific GLP-1/GLP-2 receptor agonist) program is manufactured in Korea and China, and the drug substances for our RT-111 (ustekinumab biosimilar) and RT-105 (adalimumab biosimilar) programs are manufactured in Korea. The drug substance for our RT-102 (parathyroid hormone) and RT-110 programs is manufactured in the United States.

Current or future tariffs will result in increased research and development and manufacturing expenses, including with respect to increased costs associated with drug substances, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing or collaborations on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our collaborators or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to

engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, collaborators and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have heightened and may continue to heighten the risks related to the other risk factors described in our Annual Report for the fiscal year ended December 31, 2024.

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).
4.1	Form of Registration Rights Agreement, dated October 16, 2025, by and between Rani Therapeutics Holdings, Inc. and
	the Purchasers (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the
	SEC on October 17, 2025).
4.2	Form of Common Stock Warrant (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-
	K, filed with the SEC on October 17, 2025).
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K,
	filed with the SEC on October 17, 2025).
10.1*	Collaboration and License Agreement by and between Rani Therapeutics Holdings, Inc. and Chugai Pharmaceutical Co.,
	Ltd. dated October 16, 2025.+
10.2*	First Amendment to Loan and Security Agreement and Supplement, by and among Rani Therapeutics, LLC, Rani
	Therapeutics Holdings, Inc., Rani Management Services, Inc., and Avenue Venture Opportunities Fund, L.P., dated
21.14	September 30, 2025.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act
21.2*	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
32.1*†	of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as
32.1	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
101.1115	are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
101.5011	Cover Page Interactive Data File (embedded within the Inline XBRL document)
101	cover ruge interactive Butter in (embedded within the finite ABICE document)

* Filed herewith.

- + Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted as the Registrant has determined that (i) the omitted information is not material and (ii) the omitted information is of the type that the Registrant customarily and actually treats as private or confidential. The Registrant agrees to furnish supplementally an unredacted copy of any exhibit to the Securities and Exchange Commission upon request; provided, however, that the Registrant may request confidential treatment of omitted items.

 The certifications attached as Exhibit 32.1 which accompanies this Quarterly Report on Form 10-Q, are not deemed filed with
- † 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.

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. /s/ Talat Imran

Talat Imran

Chief Executive Officer
(Principal Executive Officer) Date: November 6, 2025 /s/ Svai Sanford

Svai Sanford

Chief Financial Officer

(Principal Financial and Accounting Officer) Date: November 6, 2025 Ву: ____

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 10.1

COLLABORATION AND LICENSE AGREEMENT

 B_{Y} and B_{ETWEEN}

RANI THERAPEUTICS, LLC

AND

Chugai Pharmaceutical Co., Ltd.

 $D_{ATED} \\$

OCTOBER 14, 2025

Clause			Page			
1.	DEFINI	TIONS	1			
2.	Colla	COLLABORATION SCOPE AND GOVERNANCE			6	
	2.3	Scope of Collaboration Governance Decisions of the Committees Disbandment of the JSC		16 16	17	
3.	AUTOM	IATION OF DEVICE MANUFACTURING	19			
	3.3	Manufacturing Automation Plan [*] Manufacturing Process Diligence Progress Reports	20	20	19 20	
4.	DEVEL	DPMENT	20	0		
	4.2 4.3 4.4 4.5	Development Development Plan Development Costs Development Diligence Records and Progress Updates Provision of Know-How Cooperation Generally		20 20 21 21	21 22	
5.	REGUL	-	22			
		Regulatory Responsibilities Core Dossier Regulatory Communications and Filings		23	22	23
	5.4 5.5 5.6 5.7 5.8	Regulatory Meetings Platform Messaging Inspections Reimbursement Safety Reporting Remedial Actions		23 24 24 25	23 23	23
6.	Соммі	ERCIALIZATION	2:	5		
	6.1 6.2	Commercialization Commercial Activities		25 25		

1.	MANUFACTURE AND SUPPLY		25	
	 7.1 Manufacturing Responsibilities 7.2 Supply and Quality Agreements 7.3 Reimbursement 7.4 Manufacturing Technology Transfer 7.5 Ownership of Device Manufacturing Data 7.6 Rani Information Transfer 7.7 Update of Information Transfer 7.8 Commercial Supply 7.9 Manufacturing Audits 	26	25 25 27 28 28 28	26 26
8.	PAYMENT 2	2.8		
	 8.1 Upfront Payment 8.2 Milestone Payments 8.3 Royalty Payments 8.4 Royalty Reduction 8.5 Peer Product Adjustment 8.6 Limits 8.7 Reports 8.8 Appropriate Measure of Value 8.9 Sublicense Payments 8.10 Development and Other Costs 8.11 Payment Method 8.12 Audits 8.13 Currency Conversion 8.14 Taxes 8.15 Late Payment 8.16 Expiry of Royalty Term 	28 30 31 31 31 32 32 33 34 34	28 31 31 32 32 32 32	
9.	GRANT OF LICENSE	34		
	 9.1 License to Chugai 9.2 License to Rani 9.3 Drug Licensee Restrictions 9.4 Sublicensing 9.5 Subcontracting 9.6 Trademarks 9.7 Retained Rights 9.8 Confirmatory Patent License 9.9 Exclusivity 9.10 Acquiror IP 	34 34 34 35 36 36	34	
10.	Intellectual Property	36		

Page ii

	10.1 Background IP		36				
	10.2 Program Inventions			36			
	10.3 Data		37				
	10.4 Prosecution and Maintenance			37			
	10.5 Enforcement		38				
	10.6 Defense	40					
	10.7 Third Party IP		41				
	10.8 Allocation of Recoveries			41			
	10.9 Employee Agreements		41				
	10.10 Patent Challenge			41			
11.	COMPOUND REPLACEMENT OPTION		4	2			
	11.1 Replacement Option Grant			42			
	11.2 Replacement Option Period			42			
	11.3 Replacement Option Exercise Notice				42		
	11.4 Scope and Limitation			43			
	11.5 Effect of Replacement			43			
	11.6 Ownership and Use of Data and IP Related t	o Or	igina	l Con	npou	nd	43
	11.7 Limitation		44		•		
12.	First Refusal Rights with Respect to Additional T	ARGE	TS	44	4		
	12.1 First Refusal Right		44				
	12.2 Negotiation of License to ROFR Product				44		
	12.3 Reinstatement of First Refusal Right				45		
13.	OPTION RIGHTS WITH RESPECT TO ADDITIONAL TARGET	S		4:	5		
	13.1 Option Right		45				
	13.2 Grant of License to Option Product				46		
	13.3 Termination of Option Right			46			
1.4		4	,				
14.	CONFIDENTIALITY AND PUBLICATIONS	4	6				
	14.1 Confidentiality; Exceptions			46			
	14.2 Authorized Disclosure		47				
	14.3 Notification		48				
	14.4 Publications and Presentations			48			
	14.5 Terms and Conditions Confidential; Use of	Nam	e			49	
	14.6 Prior Agreement		49				
	14.7 Attorney-Client Privilege			49			
	14.8 Survival	50					
15.	REPRESENTATIONS WARRANTIES AND COVENANTS			5(0		

Page iii

	15.1 Mutual Representations and Warranties 15.2 Rani Representations and Warranties			50	50
	15.2 Kain Representations and Warranties 15.3 Chugai Representations and Warranties			53	30
	15.4 Disclaimer of Warranties15.5 Covenants		54	54	
16.	LIMITATIONS OF LIABILITY; INSURANCE		5		
	16.1 Limitations of Liability 16.2 Insurance		56 56		
17.	Indemnification	5	6		
	17.1 Indemnity17.2 Claim for Indemnification		56	57	
18.	[*]	58			
19.	TERM AND TERMINATION	5	8		
	19.1 Term		58		
	19.2 Termination		58	50	
	19.3 Effect of Termination 19.4 Survival of License to Joint IP			58	
	19.4 Survival of License to Joint IP		59	59	
	19.6 Rights to Intellectual Property		39	60	
	19.7 Insolvency		61	00	
	19.8 Additional Surviving Provisions			61	
	19.9 Additional Rights and Remedies			62	
20.	Miscellaneous	6	2		
	20.1 Affiliates	62			
	20.2 Assignment		62		
	20.3 Change of Control		62		
	20.4 Governing Law; Jurisdiction			63	
	20.5 Construction		64		
	20.6 Counterparts		64		
	20.7 Entire Agreement		64 64		
	20.8 Force Majeure 20.9 Equitable Relief		65		
	20.10 Further Assurances		03	65	
	20.11 No Set-Off			65	
	20.12 Notices		65		
	Page iv				

20.13	Relationship of the Parties	66	6
20.14	Severability	66	
20.15	Third Party Beneficiaries	66	6
20.16	Waivers and Modifications	66	6

Page v

Exhibits

Exhibit 1.6 – [*] Exhibit 3.2 – [*] Exhibit 15.2(a) – [*]

Page vi

COLLABORATION AND LICENSE AGREEMENT

PREAMBLE

This Collaboration and License Agreement (this "Agreement"), effective as of October 14, 2025 (the "Effective Date") is made by and between Rani Therapeutics, LLC, a California limited liability company having an address at 2051 Ringwood Ave, San Jose, CA 95131, USA ("Rani"), and Chugai Pharmaceutical Co., Ltd., a Japanese corporation having an address at 1-1 Nihonbashi-Muromachi 2-chome, Chuo-ku, Tokyo 103-8324 ("Chugai"). Rani and Chugai are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, Rani has developed an oral delivery device, known as the RaniPill® HC, to enable oral administration of biologics and drugs;

WHEREAS, Chugai has developed a [*] antibody [*], which is in development for hemophilia [*];

WHEREAS, the Parties desire to collaborate to develop, manufacture and commercialize an orally administered therapeutic Product (as defined herein) consisting of Rani's Device (as defined herein) containing Chugai's Compound (as defined herein) in the Field (as defined herein) in the Territory (as defined herein) in accordance with the terms and conditions hereof;

NOW, THEREFORE, in consideration of the premises and 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 U.S. Generally Accepted Accounting Principles (GAAP) or International Financial Reporting Standards (IFRS), as applicable.
- 1.2 "Action" has the meaning set forth in Section 10.5(b) (Chugai Licensed IP) of this Agreement.
- 1.3" Additional Products" has the meaning set forth in Section 8.2(c) (Milestone Payments) of this Agreement.

1

- 1.4"Additional Rights Period" has the meaning set forth in Section 12.1 (First Refusal Right) of this Agreement.
- 1.5"Additional Target Fee" has the meaning set forth in Section 12.2 (Negotiation of License to ROFR Product) of this Agreement.

1.6[*].

- 1.7" 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 more than fifty percent (50%) (or if 50% or less, 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, (i) with respect to Rani, only Rani Therapeutics Holdings, Inc. and any Person controlled by Rani Therapeutics Holdings, Inc. shall be deemed to be Affiliates of Rani, and (ii) with respect to Chugai [*].
 - 1.8" Agreement" has the meaning set forth in the preamble of this Agreement.
- 1.9 "Alliance Manager" has the meaning set forth in Section 2.2(d) (Alliance Managers) of this Agreement.
- 1.10"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.
- 1.11"Background IP" means any intellectual property rights that a Party has (i) owned or been licensed to use by such Party prior to the Effective Date of this Agreement, or (ii) acquired by such Party independently of the Collaboration and of the performance of the research, Development, Manufacture or Regulatory Activities under this Agreement, even if such intellectual property is used in or for the Collaboration or the research, Development, Manufacture or, Regulatory Activities of the Product under this Agreement.
- 1.12"Bankruptcy Code" means U.S. Bankruptcy Code (Title 11, U.S. Code Sections 101 et seq.).
- 1.13"BLA" means a Biologics License Application as defined in the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended from time to time, or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the Centralized Approval Procedure or with the applicable

2

Governmental Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure.

- 1.14"*Board Materials*" has the meaning set forth in Section 18.5 (<u>Borad Materials Delivery</u>) of this Agreement.
- 1.15"Business Day" means a day that is not a Saturday, a Sunday or a day on which banking institutions either in Tokyo, Japan or San Jose, California, are authorized by Applicable Law to remain closed.
- 1.16"Calendar Quarter" means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31.
- 1.17" Calendar Year" means each respective period of twelve (12) consecutive months ending on December 31.
- 1.18" 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 a bona fide financing of 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.
- 1.19"Chugai Device Manufacturing Data" has the meaning set forth in Section 7.5 (Ownership of Device Manufacturing Data) of this Agreement.
- 1.20" Chugai Indemnitees" has the meaning set forth in Section 17.1(b) (Indemnification by Rani) of this Agreement.
- $1.21\mbox{``Chugai Licensed IP''}$ means the Licensed Chugai Patents and the Licensed Chugai Know-How.
- 1.22" *Chugai Program Inventions*" has the meaning set forth in Section 10.2(a) (Chugai Program Inventions) of this Agreement.

3

- 1.23" Claims" has the meaning set forth in Section 17.1(a) (Indemnification by Chugai) of this Agreement.
- 1.24"CMC" means chemistry, manufacturing and controls information that is needed for INDs or other regulatory filings with FDA or other Governmental Authorities
- $1.25\mbox{``CMO"}$ means a Third Party contract development and/or manufacturing organization.
- 1.26"Collaboration" has the meaning set forth in Section 2.1 (Scope of Collaboration) of this Agreement.
 - 1.27" Commercially Reasonable Efforts" [*].
- 1.28" Committee" means the JSC and each subcommittee thereof, including the JDC.
- 1.29"Compassionate Use" means the provision of Product prior to its Regulatory Approval, to patients with a serious or life-threatening disease or condition who have no comparable or satisfactory alternative treatment options, pursuant to a regulatory mechanism or program authorized by a Governmental Authority (including the U.S. Food and Drug Administration's Expanded Access program), where such use is outside the scope of a clinical trial and is intended to provide treatment on a case-bycase or group basis. For clarity, Compassionate Use may include individual patient access, intermediate-size patient populations, or treatment protocols, to the extent permitted by Applicable Law.
 - 1.30"Completion of Manufacturing Technology Transfer" [*].
- 1.31"Compound" means Chugai's [*] antibody [*] in development for hemophilia [*].
- 1.32"Compound Claim" has the meaning set forth in Section 10.6(b) (Compound Claims) of this Agreement.
 - 1.33"Compound Manufacturing Data" [*].
 - 1.34"Compound-Related Product Manufacturing Data" [*].
 - 1.35"Compound-Specific Data" [*].
- 1.36"Confidential Information" means any Information provided orally, visually, in writing, or other form that is disclosed or otherwise provided by or on behalf of Disclosing Party to the Receiving Party in connection with this Agreement or the Prior Agreement, whether prior to, on or after the Effective Date, including the terms of

4

this Agreement, Information relating to the Compound, Device or Product (including Regulatory Filings), any exploitation of any Compound or Product, any Information with respect thereto developed by or on behalf of the Disclosing Party or its Affiliates or its or their respective (sub)licensees and the scientific, regulatory, or business affairs or other activities of either Party.

1.37"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.

1.38"Control" means, with respect to any Information or intellectual property, that the applicable Party or any of its Affiliates owns or has a license to such Information or intellectual property and has the ability to grant to the other Party access to and a license or sublicense (as applicable) to such Information or intellectual property as set forth herein without (i) violating the terms of any agreement with any Third Party as of the time such Party would first be required hereunder to grant such access and license or sublicense, or, for intellectual property acquired after the Effective Date, or (ii) requiring any payment (whether or not then due and payable) unless the other Party agrees in writing to be responsible for such payment.

1.39"Core Dossier" has the meaning set forth in Section 5.2 (Core Dossier) of this Agreement.

1.40"Cover", "Covered" or "Covering" means, with respect to a Product and a Licensed Rani Patent in a given country, that, in the absence of a (sub)license under or ownership of such Licensed Rani Patent, the using, offering to sell, selling or importing of such Product would infringe a Valid Claim of such Licensed Rani Patent in such country.

1.41"Debar", "Debarred" or "Debarment" means (i) being debarred, or being subject to a pending debarment, pursuant to section 306 of the FDCA, 21 U.S.C. § 335a, (ii) 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, (iii) being disqualified by any government or regulatory agency from performing specific services, or being subject to a pending disqualification proceeding, (iv) 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, (v) 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, (vi) being subject to the US Department of Commerce's Bureau of

5

Industry and Security's Entity List or Unverified List, or (vii) the subject of any similar proceedings or sanction of any Governmental Authority in any jurisdiction.

- 1.42"Develop" or "Development" means to develop (including preclinical, clinical, and CMC development), analyze, test and conduct preclinical and clinical studies 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" shall have correlative meanings.
- 1.43"Development Costs" means Rani's (and its Affiliates') External Costs attributable to Development of the Product in the Field in accordance with the Development Plan.
- 1.44"Development Milestone" has the meaning set forth in Section 8.2 (Milestone Payments) of this Agreement.
- 1.45" Development Plan" has the meaning set forth in Section 4.2 (Development Plan) of this Agreement.
 - 1.46"Device" means the RaniPill® HC (high capacity) oral delivery device [*].
 - 1.47"Device Manufacturing Data" [*].
 - 1.48"Device-Related Product Manufacturing Data" [*].
- 1.49" Disclosing Party" has the meaning set forth in Section 14.1 (Confidentiality; Exceptions) of this Agreement.
 - 1.50" Dollars" or "\$" means U.S. Dollars.
- 1.51"Drug Licensee" has the meaning set forth in Section 9.3 (Drug Licensee Restrictions) of this Agreement.
- 1.52" Effective Date" has the meaning set forth in the preamble to this Agreement.
- 1.53"EMA" means the European Medicines Agency, and any successor agency thereto.
- 1.54"European Union" or "EU" means those countries that are member states of the European Union, as such may change from time to time.
- 1.55"Executive Officer" has the meaning set forth in Section 2.3(b) (Escalation to Executives) of this Agreement.

6

- 1.56" Exercise Notice" has the meaning set forth in Section 12.1 (First Refusal Right) of this Agreement.
- 1.57" Exercise Period" has the meaning set forth in Section 12.1 (First Refusal Right) of this Agreement.
 - 1.58"External Costs" [*].
- 1.59 "FDA" means the U.S. Food and Drug Administration, and any successor agency thereto.
 - 1.60"Field" means any and all uses of the Compound in humans.
 - 1.61"Financing" [*].
 - 1.62"Financing Date" [*].
- 1.63"First Commercial Sale" means the first commercial sale of Product in the applicable country or territory by or under the authority of Chugai or its Affiliate or Sublicensee to a Third Party for consumption by an end user after receipt of all applicable Regulatory Approvals. [*].
- 1.64 "Force Majeure" has the meaning set forth in Section 20.8 (Force Majeure) of this Agreement.
- 1.65"GLP" means the current good laboratory practices applicable from time to time to Development activities with respect to a Product or any intermediate thereof pursuant to Applicable Law.
- 1.66"GMP" means the current good manufacturing practices applicable from time to time to Development activities with respect to a Product or any intermediate thereof pursuant to Applicable Law.
- 1.67"Governmental Authority" means any government administrative agency, commission or other governmental authority, body or instrumentality, or any multinational, federal, state, local, domestic or foreign governmental regulatory body.
- 1.68"*ICC*" has the meaning set forth in Section 20.4 (Governing Law; Jurisdiction) of this Agreement.
- 1.69"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 to any jurisdiction other than the United States, an equivalent filing.
- 1.70"Indemnified Party" has the meaning set forth in Section 17.2 (Claim for Indemnification) of this Agreement.

7

1.71" *Indemnifying Party*" has the meaning set forth in Section 17.2 (Claim for Indemnification) of this Agreement.

1.72" Indication" means, with respect to a Product, a use to which such Product is intended to be put for the treatment, prevention, or cure of a distinct recognized disease or condition, which, (a) for a clinical trial for such Product, would be the use of such Product for which such clinical trial is intended to determine safety or effectiveness and (b) if such Product obtains Regulatory Approval in the U.S., would be reflected in the "Indications and Usage" section of labeling pursuant to 21 C.F.R. §201.57(c)(2) or, to the extent applicable, any comparable labeling section outside the U.S., in each case ((a) and (b)), subject to the following: (i) variants, subtypes, subdivisions, or subclassifications of the same disease or condition are not additional Indications for such Product, (ii) different stages of the same disease or condition are not additional Indications for such Product, (iii) uses of such Product for the same disease or condition for different populations or population sub-types are not additional Indications for such Product, (iv) the approved use of such Product for such disease or condition in different combinations or co-administration of treatments are not additional Indications for such Product (e.g., monotherapy vs. add-on or combination therapy with another agent in the same disease), (v) the approved use of such Product for such disease or condition in a different line of treatment or a different temporal position in a treatment algorithm for the same disease or condition (e.g., first line vs. second line therapy in the same disease or condition) are not additional Indications for such Product, and (vi) different biomarker statuses with respect to the same disease or condition are not additional Indications for such Product.

1.73" *Indirect Taxes*" has the meaning set forth in Section 8.14(b) (Taxes) of this Agreement.

1.74"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.

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

1.76"Insolvency Event" means, with respect to any Party, the occurrence of any of the following: (i) such Party shall commence a voluntary case concerning itself under any bankruptcy, liquidation or insolvency code; (ii) an involuntary case is commenced against such Party and the petition is not dismissed within [*] after commencement of the case; (iii) 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

8

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 [*]; (iv) any order of relief or other order approving any such case or proceeding is entered; (v) such Party is adjudicated insolvent or bankrupt; (vi) such Party suffers any appointment of any court-appointed custodian, receiver or the like for it or all or substantially all of its property to continue undischarged or unstayed for a period of [*]; (vii) such Party makes a general assignment for the benefit of creditors; or (viii) such Party shall call a meeting of its creditors generally with a view to arranging a compromise or adjustment of its debts; or (x) any corporate, limited liability company, partnership or individual action, as applicable, is taken by such Party for the specific purpose of effecting any of the foregoing.

- 1.77" JDC" has the meaning set forth in Section 2.2(c) (Joint Development Committee) of this Agreement.
- 1.78"Joint Patent Rights" means the Patent Rights jointly owned by the Parties with respect to Joint Program Inventions.
- 1.79"Joint Program Inventions" has the meaning set forth in Section 10.2(c) (Joint Program Inventions) of this Agreement.
- 1.80" *Joint Steering Committee*" or "*JSC*" has the meaning set forth in Section 2.2(a) (Joint Steering Committee) of this Agreement.
- 1.81"Licensed Chugai Know-How" means Information Controlled by Chugai or its Affiliates on or after the Effective Date (including Program Inventions) that are [*] for Rani to perform its obligations under this Agreement.
- 1.82" *Licensed Chugai Patents*" means all Patent Rights Controlled by Chugai or its Affiliates on or after the Effective Date, in each case, that are [*] for Rani to perform its obligations under this Agreement.
- 1.83"Licensed Rani Know-How" means Information Controlled by Rani or its Affiliates on or after the Effective Date [*] that are [*] for the Development, Manufacture or commercialization of the Device and Product in the Field in the Territory.
- 1.84"Licensed Rani Patents" means any Patent Right Controlled by Rani or its Affiliates on or after the Effective Date, in each case that (i) would (absent the licenses granted herein) be infringed by the Development, Manufacture or commercialization of Product in the Field in the Territory or (ii) are [*] for the Development, Manufacture or commercialization of the Device and Product in the Field in the Territory. For purposes of determining whether a patent application falls within clause (i) of this definition, a patent application shall be considered "infringed" if its pending claims would be

9

infringed if issued as then currently set forth in the patent application. The Licensed Rani Patents in existence as of the Effective Date are listed on Exhibit 15.2(a).

- 1.85"Licensed Rani Trademark" has the meaning set forth in Section 9.6(b) (Licensed Rani Trademark) of this Agreement.
- 1.86"Losses" has the meaning set forth in Section 17.1(a) (Indemnification by Chugai) of this Agreement.
- 1.87"Manufacture" or "Manufacturing" means performing all steps of the manufacturing of a Compound, Device or Product, as applicable, including: [*].
- 1.88"Manufacturing Automation Plan" has the meaning set forth in Section 3.1 (Manufacturing Automation Plan) of this Agreement.
- 1.89"Manufacturing Costs" means, with respect to the Device or Product (a) all costs actually incurred by Rani in support of or in connection with the Manufacture (other than secondary packaging) or supply of such Device or Product as determined under full absorption costing methodology as per the Accounting Standards and the methodology employed by Rani for other devices or products [*].
- 1.90"Manufacturing Technology Transfer" has the meaning set forth in Section 7.4 (Manufacturing Technology Transfer) of this Agreement.
- 1.91"Manufacturing Technology Transfer Plan" has the meaning set forth in Section 7.4 (Manufacturing Technology Transfer) of this Agreement.
- 1.92" *Milestone Event*" has the meaning set forth in Section 8.2 (Milestone Payments) of this Agreement.
- 1.93" Milestone Payment" has the meaning set forth in Section 8.2 (Milestone Payments) of this Agreement.
- 1.94"Named Patient Program" means a regulatory pathway that permits the supply of Product, prior to its Regulatory Approval, in response to unsolicited requests from a qualified healthcare professional for the treatment of an individual patient in accordance with Applicable Law of the relevant jurisdiction.
- 1.95"Negotiation Period" has the meaning set forth in Section12.2 (Negotiation of License to ROFR Product) of this Agreement.
 - 1.96"Net Sales" [*].
- $1.97\mbox{``}OFAC\mbox{''}$ has the meaning set forth in Section 1.41 (Debar) of this Agreement.

10

1.98" Offer Notice" has the meaning set forth in Section 12.1 (First Refusal Right) of this Agreement.

1.99" Oral Delivery Data" [*].

- 1.100" Oral Delivery Technology" means the RaniPill® technology for the oral delivery of biologics and drugs for therapeutic purposes Controlled by Rani on or after the Effective Date [*].
- 1.101"Original Compound" has the meaning set forth in Section 11.1 (Replacement Option Grant) of this Agreement.
- 1.102 "Party" or "Parties" has the meaning set forth in the preamble to this Agreement.
- 1.103" Party Vote" has the meaning set forth in Section 2.3(a) (Voting; Consensus) of this Agreement.
- 1.104" Patent Challenge" has the meaning set forth in Section 10.10 (Patent Challenge) of this Agreement.
- 1.105"Patent Rights" 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, reexaminations 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.
 - 1.106"Peer Product" [*].
- 1.107"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.

11

- 1.108" Phase 1 Clinical Trial" means, with respect to the United States, any human clinical trial, the principal purpose of which is preliminary determination of safety in healthy individuals or patients as required under 21 C.F.R. §312.21(a), or, with respect to a jurisdiction other than the United States, an equivalent clinical study.
- 1.109" *Platform Messaging*" has the meaning set forth in Section 5.5 (Platform Messaging).
- 1.110"Pre-Transaction Entities" means, with respect to a Change of Control of a Party, (a) the Third Party with which such Party or its Affiliate merges or consolidates with, or is acquired by, (b) any Affiliate of the Third Party that was an Affiliate of the Third Party prior to such Change of Control and (c) any successor entity to the Third Party or any Affiliate thereof after consummation of such Change of Control.
- 1.111" *Prior Agreement*" has the meaning set forth in Section 14.6 (Prior Agreement) of this Agreement.
- 1.112" *Product*" means the combination product comprising the Compound incorporated into the Device for oral administration, and excluding any active ingredients other than the Compound.
- 1.113" Product Infringement Claim" has the meaning set forth in Section 10.6(a) (Notice) of this Agreement.
 - 1.114"Product Manufacturing Data" [*].
- 1.115" Program Data" means data generated in the performance of the Development or Manufacture of the Product or other Collaboration activities [*].
- 1.116" *Program Invention*" means an invention conceived or reduced to practice during the Term in the performance of the Development or Manufacture of the Product.
 - 1.117" Rani" has the meaning set forth in the preamble to this Agreement.
- 1.118" Rani Device Manufacturing Data" has the meaning set forth in Section 7.5 (Ownership of Device Manufacturing Data) of this Agreement.
- 1.119"Rani Indemnitees" has the meaning set forth in Section 17.1(a) (Indemnification by Chugai) of this Agreement.
- 1.120" Rani Licensed IP" means the Licensed Rani Patents and Licensed Rani Know-How, including Rani's interest in the Joint Patent Rights and Rani's interest in the Joint Program Inventions.
- 1.121"Rani Program Inventions" has the meaning set forth in Section 10.2(b) (Rani Program Inventions) of this Agreement.

12

- 1.122"Receiving Party" has the meaning set forth in Section 14.1 (Confidentiality; Exceptions) of this Agreement.
- 1.123"*Recoveries*" means all cash amounts 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 Activities*" has the meaning set forth in Section 5.1 (Regulatory Responsibilities) of this Agreement.
- 1.125"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, including, where applicable, (i) [*] pricing or reimbursement approval in such country or other jurisdiction, (ii) pre-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (iii) approval of Product labeling.
- 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, including master file for devices, investigational device exemption, premarket approval, IND, new drug application, BLA, any components or portions of the foregoing, and the equivalents of the foregoing in any jurisdiction.
- 1.127" Remedial Action" means a recall, market suspension or market withdrawal of the Product or any lots thereof.
- 1.128"Replacement Compound" has the meaning set forth in Section 11.1 (Replacement Option Grant) of this Agreement.
- 1.129"Replacement Effective Date" has the meaning set forth in Section 11.3 (Exercise Notice) of this Agreement.
- 1.130"Replacement Option" has the meaning set forth in Section 11.1 (Replacement Option Grant) of this Agreement.
- 1.131"Replacement Option Exercise Notice" has the meaning set forth in Section 11.3 (Replacement Option Exercise Notice) of this Agreement.
- 1.132" Replacement Option Period" has the meaning set forth in Section 11.2 (Replacement Option Period) of this Agreement.
- 1.133 "Representatives" has the meaning set forth in Section 14.2 (Authorized Disclosure) of this Agreement.

13

1.134[*]. 1.135[*].

- 1.136" ROFR Product" has the meaning set forth in Section 12.1 (First Refusal Right) of this Agreement.
- 1.137"Royalty Payments" has the meaning set forth in Section 8.3 (Royalty Payments) of this Agreement.
- 1.138"Royalty Term" has the meaning set forth in Section 8.3 (Royalty Payments) of this Agreement.
- 1.139"Sales Milestone" has the meaning set forth in Section 8.2 (Milestone Payments) of this Agreement.
- 1.140"Segregate" means, with respect to a Party undergoing a Change of Control, establishing and enforcing internal processes, policies, procedures, and systems to segregate the Development, Manufacture or commercialization of Products under this Agreement from all the development, manufacturing and commercialization activities of the Pre-Transaction Entities, including ensuring that (i) Pre-Transaction Entities do not obtain any access to any Confidential Information related to the Products and Compound, (ii) Pre-Transaction Entities do not incorporate, reference or practice (other than indirectly through the acquired Party and its Affiliates existing prior to the Change of Control), any Patent Rights, Information, or Confidential Information of the Party not undergoing a Change of Control or its pre-existing Affiliates in connection with the development, manufacture or commercialization activities of the Pre-Transaction Entities [*].
- 1.141"Seller" has the meaning set forth in Section 1.96 (Net Sales) of this Agreement.

1.142[*].

1.143[*].

1.144[*].

1.145"Subcontractor" means a Third Party contractor (including contract research organizations, CMOs, or Third Party distributors) engaged by a Party or its Affiliates or Sublicensees 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 Sublicensees or exercise certain rights on behalf of such Party or its Affiliates or Sublicensees, in each case, under this Agreement.

14

- 1.146"Sublicensee" means a Third Party to which Chugai or its Affiliate has granted or grants rights under the rights granted to Chugai pursuant to Section 9.1 (License to Chugai) of this Agreement, 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 (even if granted such sublicense or other rights).
- 1.147"*Taxes*" means any income, license, excise, stamp, premium, environmental, duty, franchise, profits, withholding, real property, personal property, sales, use, transfer, registration, ad valorem, value added, alternative or add-on minimum or estimated tax or other tax of any kind whatsoever, including any interest, penalty or addition thereto, whether disputed or not.
- 1.148"*Technology Transfer Milestone*" has the meaning set forth in Section 8.2 (Milestone Payments) of this Agreement.
- 1.149 "Term" has the meaning set forth in Section 19.1 (Term) of this Agreement.
 - 1.150"Territory" means the entire world.
- 1.151 "Third Party" means any Person other than a Party or an Affiliate of a Party.
- 1.152" Third Party License Fees" has the meaning set forth in Section 8.9 (Sublicense Payments) of this Agreement.
 - 1.153"Transenteric" [*].
- 1.154"*United States*" or "*US*" means the United States of America, including its territories and possessions (including the District of Columbia and Puerto Rico).
- 1.155" *Upfront Payment*" has the meaning set forth in Section 8.1 (Upfront Payment) of this Agreement.
- 1.156" Valid Claim" means a claim of an issued, unexpired and in-force 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.
- 1.157 "Voting Securities" means securities entitled to be voted generally or in the election of directors of an entity.

15

2. COLLABORATION SCOPE AND GOVERNANCE

2.1 <u>Scope of Collaboration</u>. The Parties shall collaborate with respect to the Development and Manufacture and supply of the Device and Product in the Field in the Territory in accordance with the terms and conditions of this Agreement (the "Collaboration").

2.2Governance.

(a) Joint Steering Committee. Promptly following the Effective Date, the Parties shall establish a Joint Steering Committee (the "Joint Steering Committee" or "JSC") to (i) facilitate information-sharing and coordination with respect to the status and progress of the Development and Manufacture and supply of the Device and Product in the Field in the Territory, (ii) provide a forum for discussing and resolving issues with respect to the conduct of the Collaboration, and (iii) establish and delegate specifically-defined duties to the JDC on an "as-needed" basis to review, discuss, and, as applicable, oversee particular projects or activities, and receive and discuss reports from the JDC and provide guidance regarding the same. The JSC shall be comprised of an equal number of members from each Party, each of whom shall have the appropriate experience, expertise, and decision-making authority to perform his or her responsibilities on the JSC. Either Party may replace its respective JSC members at any time upon prior written notice to the other Party. Other employees of the Parties may attend JSC meetings, but a Party shall not bring a Third Party to a JSC meeting without the other Party's prior consent. Such non-JSC member participants will have no voting authority at the JSC. Each Party shall ensure that all of its JSC members, and all of its non-member employees and all non-employee Third Parties attending any JSC meeting, are bound by obligations of non-use and confidentiality that are at least as protective of the other Party's Confidential Information as are those set forth in Article 14 (Confidentiality and Publications). The JSC 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.

(b) JSC Meetings. The JSC shall meet [*] every Calendar Year thereafter, or such other frequency as mutually agreed by the Parties. JSC meetings may be conducted by telephone, videoconference or in person as determined by the Parties. Either Party may request a meeting of the JSC (in person, by videoconference or teleconference) with reasonable prior written notice (it being agreed that at least [*] shall constitute reasonable notice, unless a matter is exigent) and the Parties shall reasonably cooperate to meet promptly. Each Party shall appoint [*] its JSC representatives to act as a co-chairperson of the JSC. [*]. The JSC co-chairpersons (or, at the election of the JSC co-chairpersons, the Alliance Managers) shall jointly prepare and circulate agendas

16

to JSC representatives at least [*] before each JSC meeting (other than a special meeting as described above) and shall direct the preparation of meeting minutes after each JSC meeting, which shall be approved by the JSC co-chairpersons and circulated to other JSC representatives within [*] after such meeting. Except as expressly set forth in this Section 2.2(b) (JSC Meetings), no JSC co-chairperson shall have any rights or powers greater than those of any other JSC member.

- (c) *Joint Development Committee*. Promptly following the establishment of the JSC, the JSC shall establish a joint development committee ("*JDC*"), which will be a subcommittee of the JSC. Each Party shall report to the JDC on all material issues relating to the Development of the Product at the next JDC meeting after such issues arise. Each Party will bear the expense of its respective JDC members' participation in JDC meetings. The JDC shall meet [*], or such other frequency as mutually agreed by the Parties. The JDC will dissolve upon completion of all Development activities in the Development Plan. The JDC will have the following responsibilities:
 - (i) facilitate the exchange of information between the Parties under the Development Plan;
 - (ii)oversee, coordinate and ensure successful completion of the Manufacturing Automation Plan;
 - (iii)oversee, coordinate and ensure successful completion of the Manufacturing Technology Transfer Plan; and
 - (iv)perform such other non-decision making functions as appropriate to further the purposes of this Agreement, as directed by the JSC, or as specified in this Agreement.
- (d) Alliance Managers. Promptly following the Effective Date, each of Rani and Chugai shall appoint a person within their organization to act as its respective alliance manager to coordinate between the Parties with respect to the Collaboration (each, an "Alliance Manager"). Each Party may replace its respective Alliance Manager 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.

2.3 Decisions of the Committees.

(a) *Voting; Consensus*. Each Party's representatives on the JSC and each subcommittee will, collectively, have one vote (the "*Party Vote*") on all matters within the authority of and brought before such Committee for a decision. The JSC and each subcommittee shall make decisions as to matters within its jurisdiction by unanimous Party Vote, which may be reflected in the

17

minutes of the Committee meeting or by an action by written consent signed by a member appointed by each Party or his or her designee identified in writing.

- (b) Escalation to JSC. Any disagreement between the representatives of Rani and Chugai with respect to matters within the scope of authority of the Alliance Managers or the JDC that cannot be resolved after good faith efforts within [*] after such disagreement is first raised in writing, either via email or Committee meetings, by a Party representative shall, at the election of either Party, be submitted to the JSC for resolution. If the JSC is unable to resolve any such disagreement referred to it by the Alliance Managers or the JDC, or any disagreement with respect to the matters within the scope of the JSC; authority or any other dispute between the Parties that may be referred to the JSC, in each case, using good faith efforts within a period of [*] from such referral or the start of such disagreement, as applicable, then either Party may immediately refer such matter for resolution to the [*] or their respective designees from senior management with decision-making authority over such matter (such executives or such designees, each, an "Executive Officer").
- (c) Escalation to Executives. In the event that the Executive Officers are unable to resolve any dispute referred to them pursuant to Section 2.3(b) (Escalation to JSC) within [*] after such dispute was referred to the Executive Officers, then the provisions of Section 2.3(d) (Final Decision-Making Authority) will apply.
- (d) Final Decision-Making Authority. If the Executive Officers are unable to reach agreement on any disputed matter so referred to them within [*] after such matter was referred to them (or such longer period as the Executive Officers may agree upon), then the Party specified below shall, subject to Section 2.3(e) (Limitations on Decision Making Authority) and except to the extent otherwise specified in this Agreement, have final decision-making authority with respect to the matters specified below, but any such decision must be (to the extent applicable) consistent with such Party's obligations under this Agreement [*].
- (e) Limitations on Decision Making Authority. Notwithstanding the foregoing provisions of this Section 2.3 (Decisions of the Committee), neither Party may exercise its right to finally resolve a dispute:
 - (i) in a manner that excuses such Party from any of its obligations specifically enumerated under this Agreement;
 - (ii)in a manner that conflicts with the any of the express terms or conditions of this Agreement (including any obligation to comply with Applicable Law);

18

- (iii)in a manner that negates any consent rights or other rights specifically allocated to the other Party under this Agreement;
- (iv)if the provisions of this Agreement specify that mutual agreement of the Parties is required for such matter;
- (v)if the provisions of this Agreement specify that a specific Party has a consent right or final decision making authority for such matter;
 - (vi)involving the breach or alleged breach of this Agreement;
- (vii)in a manner that would require the other Party to perform any act that would breach any obligation to any Third Party or is inconsistent with any Applicable Law;
- (viii)to determine whether or not a Milestone Event has been achieved; or
- (ix)to otherwise expand a Party's rights or reduce a Party's obligations under this Agreement.
- 2.4<u>Disbandment of the JSC</u>. In the event of the insolvency or bankruptcy of Rani or a Change of Control of Rani, Chugai shall have the right, effective upon written notice to Rani, to either terminate its disclosure obligations to the JSC or dissolve the JSC (and any subcommittees).

3. Automation of Device Manufacturing

3.1 Manufacturing Automation Plan. Within a reasonable time after the Effective Date, the Parties shall negotiate in good faith and agree upon a manufacturing process development plan to establish a Manufacturing process capable of commercial production of Device and Product [*] (the "Manufacturing Automation Plan"). In the event the Parties are unable to reach agreement on the Manufacturing Automation Plan within a reasonable time after the Effective Date, the issues of disagreement shall be referred to the Executive Officers for resolution. If the Executive Officers are unable to reach an agreement on the issues of disagreement within [*] after such matter was referred to them (or such longer period as the Executive Officers may agree upon), Rani will have the final decision making authority on the issues of disagreement. Development and establishment of the Manufacturing process capable of commercial production of Device and Product shall be conducted in accordance with the Manufacturing Automation Plan. The Parties shall review and update the Manufacturing Automation Plan at least [*]. Any change or update to the Manufacturing Automation Plan shall require the JSC's approval. The Party proposing a change will provide the proposed change to the other Party, and such other Party shall be given at least [*] to review the change in advance of a meeting to discuss such change. The JSC shall then

19

discuss in good faith the proposed change at the next JSC meeting. If the terms of the Manufacturing Automation Plan contradict, or create inconsistencies or ambiguities with, the terms of this Agreement, then the terms of this Agreement shall govern unless agreed otherwise by the Parties.

3.2[*]

- 3.3 <u>Manufacturing Process Diligence</u>. From and after the Effective Date, Rani shall [*] establish a Manufacturing process capable of commercial production of Device and Product according to the Manufacturing Automation Plan.
- 3.4<u>Progress Reports</u>. [*] Rani shall report to Chugai through the JSC on the progress of its Manufacturing Development and related activities.

4. DEVELOPMENT

- 4.1 <u>Development</u>. The Parties shall collaborate in the Development of the Product in the Field in the Territory. Each Party shall perform the activities assigned to it in the Development Plan.
- 4.2Development Plan. Within a reasonable time after the Effective Date, the Parties shall negotiate in good faith and agree upon a multi-year development plan for the Product in the Field in the Territory (the "Development Plan"). In the event the Parties are unable to reach agreement on the Development Plan within a reasonable time after the Effective Date, the issues of disagreement shall be referred to the Executive Officers for resolution. If the Executive Officers are unable to reach an agreement on the issues of disagreement within [*] after such matter was referred to them (or such longer period as the Executive Officers may agree upon), Chugai will have the final decision making authority on the issues of disagreement. Development of the Product in the Field in the Territory shall be conducted in accordance with the Development Plan. The Parties shall review and update the Development Plan at least annually. Any change or update to the Development Plan shall require the JSC's approval The Party proposing a change will provide the proposed change to the other Party, and such other Party shall be given at least [*] to review the change in advance of meeting to discuss. The JSC shall then discuss in good faith the proposed change at the next JSC meeting. 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 unless agreed otherwise by the Parties.
 - (a) *Preclinical Development*. The Development Plan will include an allocation of preclinical activities with respect to Device and Product in accordance with this Section 4.2(a) (Preclinical Development). Chugai shall be responsible for preclinical development of the Compound. Rani shall provide Chugai with relevant preclinical study results of the Device that are [*] for the Development, Manufacture and commercialization of the Device whether or not related specifically to the Product, and to the extent conducted by Rani,

20

preclinical study results of the Product[*] for the Development, Manufacture and commercialization of the Product [*].

- (b) Clinical Development. Chugai shall be solely responsible for creating, deciding and conducting the clinical Development activities in the Development Plan and shall be the sole sponsor of the clinical trials of the Product; [*]. Rani shall, upon Chugai's reasonable request, provide Chugai with (i) information which is [*] for conducting any clinical trials [*] of the Product and (ii) any other reasonable assistance requested by Chugai concerning the foregoing.
- (c) CMC Development. The Development Plan shall include an allocation of CMC Development activities with respect to Device and Product in accordance with this Section 4.2(c) (CMC Development). Chugai shall be responsible for (i) CMC Development with respect to Compound before the Completion of Manufacturing Technology Transfer, and (ii) CMC Development with respect to Compound and Product after the Completion of Manufacturing Technology Transfer. Rani shall be responsible for (x) CMC Development with respect to Device and the Product before the Completion of Manufacturing Technology Transfer, and (y) CMC Development with respect to Device after the Completion of Manufacturing Technology Transfer. Notwithstanding the foregoing, the Parties acknowledge that the responsibilities set forth above represent the general allocation of CMC Development activities. The Parties may discuss and modify such allocation of responsibilities as such modification becomes [*] for the Development Plan; provided however, that Rani shall be responsible for establishing a Manufacturing process capable of commercial production of Device and Product. [*].
- 4.3 <u>Development Costs</u>. Chugai shall be responsible for all costs of Chugai's activities under the Development Plan. [*]. The Parties intend that Chugai will reimburse Rani for requested support that is additional to the foregoing or resource intensive; except that Chugai shall not reimburse any costs incurred by Rani for activities performed without the express request of Chugai or approval in writing by Chugai.
- 4.4<u>Development Diligence</u>. From and after the Effective Date, Chugai shall [*] Develop the Product in the Field in the Territory, consistent with the Development Plan and the terms of this Agreement. [*] Chugai shall report to Rani through the JSC on the progress of its Development, including Regulatory Activities, of the Product.
- 4.5 Records and Progress Updates. 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 and Manufacturing activities pursuant to this Agreement. Each Party shall keep the JSC regularly informed

21

of the status of all material Development and Manufacturing 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 JSC shall determine. In addition, Rani shall keep the JSC regularly informed of data and progress of the Device relevant to the Product, including safety data and adverse event data relevant to the Product.

- 4.6 <u>Provision of Know-How.</u> Following the Effective Date, the Parties shall cooperate in the sharing of Information relating to the Device and Product to the extent reasonably required to support their respective responsibilities under this Agreement, including the Development, Manufacture and commercialization of Device and Product; provided that a Party shall not be obligated to disclose any Information that is not [*] for the other Party to perform its responsibilities or exercise its rights hereunder.
- 4.7 <u>Cooperation Generally</u>. From and after the Effective Date, the Parties shall provide each other with any cooperation reasonably requested by the other to carry out the purpose and intent of this Agreement. Unless otherwise agreed by the Parties, Information shared under this Agreement shall be disclosed in the English language; provided that neither Party will be obligated to provide translations of any Information or documents written in a language other than English to the extent such Information or documents are written in a language other than English due to Applicable Law or instruction or requirement of any Governmental Authority.

5. REGULATORY

5.1 Regulatory Responsibilities. The Parties shall collaborate in the conduct of Regulatory Activities in support of the Development and Manufacture and supply of the Device and Product in the Field in the Territory. Chugai shall lead and have sole responsibility for regulatory strategy, including deciding marketing application(s) strategy, and activities related to Product, including preparing, submitting, and maintaining all Regulatory Filings for Product and interacting with Governmental Authorities with respect to Product, and Rani will have responsibility for preparing, submitting, and maintaining all Regulatory Filings for the Device and interacting with Governmental Authorities with respect to the Device ("Regulatory Activities"). Chugai shall keep Rani reasonably informed with respect to the regulatory strategy and activities for the Product as related to the Device and the Product generally, and Rani shall keep Chugai reasonably informed with respect to the regulatory strategy and activities for the Device as related to the Product and the Device generally, and shall consider in good faith any comments from Chugai regarding the foregoing. Upon reasonable request of Chugai, Rani shall provide to Chugai support of the Regulatory Activities and any Information and assistance reasonably requested by Chugai in preparing and filing required regulatory submission(s) of the Product [*]. In providing support for the Regulatory Activities, Rani may redact information to which Rani owes an obligation of confidentiality to a Third Party.

22

- 5.2<u>Core Dossier</u>. Chugai shall develop the requisite core dossier for the Product, including Manufacturing (CMC) module(s) (the "*Core Dossier*") [*]. The messaging in the Core Dossier shall be reasonably consistent with the Platform Messaging. Chugai shall prepare the draft of the Core Dossier and provide such draft to Rani for review and comment. Chugai shall reasonably consider Rani's comments in good faith. Rani shall support Chugai's preparation of the Core Dossier by providing information [*] therefor with respect to activities performed by Rani. [*].
- 5.3 Regulatory Communications and Filings. Chugai shall keep Rani reasonably informed of the status of (i) the preparation of Regulatory Filings that Chugai submits, (ii) Governmental Authority review of and correspondence regarding any such Regulatory Filings, and (iii) Regulatory Approvals that Chugai obtains with respect to the Product [*]. Chugai shall prepare all Regulatory Filings reasonably consistent with the Platform Messaging. Upon request, subject to Section 4.6 (Provision of Know-How), Chugai shall provide promptly to Rani copies of the Regulatory Filings it submits with respect to Product and/or regulatory correspondence received from Governmental Authorities with respect to Product in the Field in the Territory; [*].
- 5.4Regulatory Meetings. Chugai (i) shall keep Rani reasonably apprised of scheduled meetings and interactions with Governmental Authorities, including feedback from Governmental Authorities regarding Product, (ii) shall consult with Rani reasonably in advance of any such regulatory meetings or interactions where the Oral Delivery Technology or Manufacturing of the Device is an agenda item or anticipated to be discussed, and (iii) shall consider any timely recommendations made by Rani in preparation for such meetings or interactions; [*]. Upon the request of Chugai for Rani to attend and participate in a regulatory meeting with a Governmental Authority with respect to Product in the Field in the Territory, the Parties shall cooperate and [*] facilitate such attendance and participation.
- 5.5 <u>Platform Messaging</u>. The Parties shall discuss in good faith and agree upon messaging to be used by Chugai, its Affiliates and Sublicensees with respect to describing the Oral Delivery Technology in Regulatory Filings, meetings and correspondence with Governmental Authorities with respect to Product in the Field in the Territory (the "*Platform Messaging*"). In no event shall Platform Messaging include any messaging with respect to the Compound. 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.
- 5.6<u>Inspections</u>. Each Party shall 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 the Device or Product in the Field in the Territory. 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

23

reasonably requested or required. The Parties shall 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 the Device or Product, and not general inspections by Governmental Authorities.

5.7Reimbursement. [*].

5.8Safety Reporting.

- (a) As the sole sponsor of clinical trials of the Product, Chugai shall be responsible for processing and evaluation of any adverse events occurring in a clinical trial of the Product, and Rani shall, upon Chugai's request, provide reasonable assistance to Chugai in such processing and evaluation from the perspective of Device. For clarity, Chugai shall have the final say regarding assessment of causality and medical evaluation with respect to Product.
- (b) The Parties shall reasonably cooperate with each other regarding pharmacovigilance matters with respect to Product and Device to the extent reasonably required to enable the other Party to comply with Applicable Law. From and after the Effective Date, unless otherwise agreed in the Development Plan, Chugai shall be responsible for reporting to the relevant Governmental Authorities all adverse events arising from the Development or commercialization of the Product, to the extent required by and in accordance with Applicable Law. Upon becoming aware of any safety information relating to Device, Chugai shall promptly report such information to Rani. Upon becoming aware of any safety information relating to Device that is relevant to the Product, Rani shall promptly report such safety information to Chugai. Rani may include pharmacovigilance Information regarding the Product in filings and communications with Governmental Authorities where relevant with respect to review or consideration of the Oral Delivery Technology, alone or with a compound other than the Compound; provided that in no event shall Rani include any pharmacovigilance Information regarding the Compound (including Compound-Specific Data or any other Compound-specific Information) in filings and communications with Governmental Authorities.

24

5.9Remedial 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 Device, including the 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 with respect to the Product. The Parties shall, and shall ensure that their Affiliates and (Sub)licensees shall, maintain adequate records to permit the Parties to trace the Manufacture, distribution and use of the Device and Product. The Parties shall discuss at JSC any matters relating to any Remedial Action with respect to Product, including the decision to commence such Remedial Action. Chugai shall have sole control over the conduct of such Remedial Action; provided however, that Rani may take immediate action under exigent circumstances or as necessary to protect patient safety.

6. COMMERCIALIZATION

6.1 <u>Commercialization</u>. Chugai shall have the sole responsibility for commercialization of the Product in the Field in the Territory, at its own cost. For the avoidance of doubt, this Article 6 (Commercialization) shall not apply to any activities related to the establishment of a Manufacturing process for the commercial production of Device and Product.

6.2<u>Commercial Activities</u>. Chugai's commercialization responsibilities shall include, directly or indirectly, conducting promotion, sales and distribution activities, including booking sales, taking orders and distributing, contracting, handling of returns, handling all aspects of order processing, invoicing and collecting, warehousing, documenting inventory and receivables, call reporting, handling data regarding sales to hospitals and other end users, patient support programs, and handling all other customer service-related functions. Chugai shall be solely responsible for its costs incurred in its commercialization of the Product in the Field in the Territory.

7. MANUFACTURE AND SUPPLY

7.1 Manufacturing Responsibilities. Chugai shall be solely responsible for Manufacturing and supplying the Compound for all Development of the Product in the Territory at Chugai's cost as set forth in the Development Plan. Rani shall be solely responsible for Manufacturing and supplying the Product (including Manufacturing the Device and incorporating Compound into the Device) for all Development and commercialization of the Product in the Territory to the extent set forth in the Development Plan. [*]. Notwithstanding the foregoing, with respect to the packaging of Product, (i) Rani shall be responsible for primary packaging of Product, and (ii) Chugai shall be solely responsible for all secondary packaging of Product and distribution and supply chain of final packaged Product.

7.2<u>Supply and Quality Agreements</u>. Within a reasonable time after the Effective Date (or such other period of time agreed to by the Parties), the Parties shall

25

negotiate and execute one or more clinical supply agreements and quality agreements to govern (i) the Manufacturing and supply to Rani of Compound by Chugai (or its CMO), (ii) the Manufacturing and supply to Chugai of Device by Rani (or its CMO) (if any), and (iii) the Manufacturing and supply to Chugai of Product by Rani (or its CMO). Each Party may use a CMO to perform its Manufacturing and supply obligations hereunder, subject to the other terms and conditions of this Agreement. If Rani uses a CMO to Manufacture and supply the Device and/or Product to Chugai, then, at the request of Chugai, Rani shall facilitate Chugai contracting directly with the CMO to obtain supply of Device and/or Product. [*].

7.3Reimbursement. [*].

- 7.4 Manufacturing Technology Transfer. Upon the request of Chugai, the Parties shall negotiate in good faith and agree upon a Manufacturing technology transfer plan (the "Manufacturing Technology Transfer Plan") that includes a technology transfer of the Device and Product Manufacturing process to a mutually agreed CMO, Chugai, Chugai Affiliate(s) and/or Sublicensee(s) (the "Manufacturing Technology Transfer"). [*]. The Manufacturing Technology Transfer Plan is agreed upon. From and after the Manufacturing Technology Transfer, if requested by Chugai, Rani shall continue to perform the Device component Manufacturing and supply [*], itself or through a CMO of its choosing, and supply such Device components to the mutually agreed CMO, Chugai, Chugai Affiliate(s) and/or Sublicensee(s). [*].
 - (a) *Manufacturing Transfer Costs*. Chugai shall be responsible for all costs of Chugai's activities under the Manufacturing Technology Transfer Plan. [*].
 - (b) *Post-Transfer Support*. After completing the Manufacturing Technology Transfer, Rani shall continue to collaborate and provide answers and reasonable support to Chugai, Chugai's Affiliate(s), Sublicensees, and/or to the mutually agreed CMO, in connection with CMC activities including CMC Development, production or Manufacture of Device or Product.
- 7.5 Ownership of Device Manufacturing Data. All Device Manufacturing Data existing at, and all Device Manufacturing Data generated by, Rani following the initiation of the Manufacturing Technology Transfer shall be owned by Rani ("Rani Device Manufacturing Data"). All Device Manufacturing Data generated by Chugai following the initiation of the Manufacturing Technology Transfer shall be owned by Chugai ("Chugai Device Manufacturing Data"). Each Party shall grant the other Party a right of reference to its respective Device Manufacturing Data to the extent such data is [*] for (i) either Party to perform its activities under this Agreement, or (ii) Rani to conduct Regulatory or Manufacturing activities relating to the Device, such right of reference not to be unreasonably withheld, conditioned, or delayed.

26

7.6 Rani Information Transfer. Without limiting the foregoing, for no additional consideration (including no reimbursement for any costs or expenses incurred by or on behalf of Rani), Rani shall transfer and deliver to Chugai in the original format (Microsoft Excel, Word, PowerPoint, etc.) in a method agreed to by the Parties' IT departments (e.g., FTP, physical hard disk)within [*] following the Effective Date, download access to the relevant contents of the diligence data room. Rani further agrees to disclose and make available to Chugai such Rani know-how, data, Information, and technical expertise that are (i) related to the Device or Product, (ii) [*] for Chugai or its relevant Affiliate(s) or Sublicensee(s) to conduct or perform its obligations and exercise its rights under this Agreement, and (iii) in Rani's or any of its Affiliates' possession or Control, subject to any duties of confidentiality owed to any Third Parties. Such disclosure shall be made on a timely basis, and may include written, oral, electronic, or other forms of communication. In addition, Rani shall provide Chugai with reasonable access to Rani personnel with relevant expertise to explain any Licensed Rani Know-How transferred in accordance with this Section 7.6 (Rani Information Transfer). Without limiting the foregoing, Rani shall transfer and deliver to Chugai the following:

(a) within [*] following the Effective Date, to the extent not included in the diligence data room:

(i) any formal and informal, written or electronic correspondence or communications with or from the relevant Governmental Authority, as well as minutes of any material meetings, telephone conferences, or discussions with the relevant Governmental Authority in relation to the Device:

(ii)any quality assurance related documents [*] relating to the Device; and

(b) within [*] following the Effective Date, copies of the following [*] to the extent not already provided:

(i) copies of Licensed Rani Know-How in reasonably sufficient detail in order for a reasonably skilled Person to practice such Licensed Rani Know-How; provided however, that Rani shall not be required to provide copies of Licensed Rani Know-How relating to Manufacturing of the Device unless and until Chugai can demonstrate to Rani a reasonable need or use for such Licensed Rani Know-How; provided that "reasonable need or use" shall include, without limitation, activities [*] for Manufacturing Technology Transfer and Chugai's Regulatory Activities related to the Product,

(ii)copies of any and all research data, CMC data, preclinical and nonclinical data, and clinical data, and all other documentation submitted, or required to be submitted, to Governmental Authorities to support, obtain, or maintain any Regulatory Approval for a pharmaceutical

27

product or administration device, or otherwise included in any Regulatory Filings for a pharmaceutical product or administration device, [*],

- (c) in each case (Sections 7.6(a)-7.6(c)) that are: (i) related to the Device or Product, (ii) [*] for Chugai or its relevant Affiliate(s) or Sublicensee(s) to conduct or perform its obligations and exercise its rights under this Agreement, and (iii) in Rani's or any of its Affiliates' possession or Control. In addition, Rani shall provide Chugai with reasonable access to Rani personnel with relevant expertise to explain any Licensed Rani Know-How transferred in accordance with this Section 7.6 (Rani Information Transfer).
- 7.7 Update of Information Transfer. Following the completion of the transfer and delivery of the information covered by Section 7.6 (Rani Information Transfer) [*], Rani shall collect any new information that would have been covered by the subject matter of Section 7.6 (Rani Information Transfer) had it existed prior to the completion of such transfer and delivery, and transfer and deliver such new information to Chugai in the original format (Microsoft Excel, Word, PowerPoint, etc.) in a method agreed to by the Parties' IT departments (e.g., FTP, physical hard disk).
- 7.8<u>Commercial Supply.</u> In the event that the Completion of Manufacturing Technology Transfer does not occur prior to [*], Rani shall be responsible for Manufacturing and supplying Product, including Manufacturing of Device, for commercial use. In such case and at the request of Chugai, the Parties shall negotiate in good faith and enter into a supply agreement that will govern the terms and conditions of the Manufacture and supply of Product by Rani to Chugai and its Affiliates and their Sublicensees for commercial use, along with a related quality agreement. [*].
- 7.9 Manufacturing Audits. Chugai shall have customary audit rights with respect to Rani's (and/or any CMO engaged by Rani) Manufacturing of Product, which shall be further addressed in the quality agreement. The Manufacturing process of the Device and Product, and the Device and Product supplied by Rani shall meet all quality requirements agreed by the Parties.

8. PAYMENT

- 8.1<u>Upfront Payment</u>. As partial consideration of the rights granted by Rani to Chugai hereunder, and contingent upon Rani receiving the Financing, Chugai shall pay Rani a non-refundable, non-creditable upfront payment in the amount of Ten Million U.S. Dollars (US \$10,000,000) (the "*Upfront Payment*") according to the provisions of this Section 8.1 (Upfront Payment). On or after the Financing Date, Rani shall issue an invoice for the Upfront Payment, and Chugai shall pay the Upfront Payment [*] following receipt of such invoice.
- 8.2 <u>Milestone Payments</u>. Chugai shall pay Rani the non-refundable, non-creditable, one-time milestone payments as set forth below (each a "*Milestone Payment*") upon the first achievement of each corresponding event (each corresponding

28

event, a "Technology Transfer Milestone", "Development Milestone", or "Sales Milestone" as applicable, and collectively, "Milestone Events").

Milestone Event	Milestone Payment
[*]	
[*]	[*]
[*]	[*]
Total Technology Transfer Milestones	Eighteen Million U.S. Dollars (\$18,000,000)
[*]	
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
Total Development Milestones	Fifty-Seven Million U.S. Dollars (\$57,000,000)
[*]	
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
Total Sales Milestones	One Hundred Million U.S. Dollars (\$100,000,000)

(a) Chugai shall notify Rani of the achievement of each Milestone Event [*] after Chugai becomes aware of such achievement and Rani may issue an invoice to Chugai in respect of the same. [*] after receipt of each Milestone Event invoice, Chugai shall pay the applicable Milestone Payment amount to Rani.

29

- (b) Each Technology Transfer Milestone Payment shall be paid only once on the first achievement of the applicable Technology Transfer Milestone Event by Chugai or any of its Affiliates or Sublicensees. In no event shall Chugai's obligations to make Technology Transfer Milestone Payments exceed Eighteen Million U.S. Dollars (US \$18,000,000) in the aggregate. Subject to Section 8.2(c), each Development Milestone Payment shall be paid only once on the first achievement of the applicable Development Milestone Event by Chugai or any of its Affiliates or Sublicensees with respect to the Product, regardless of how many times such Milestone Event is achieved by the Product, and in no event shall Chugai's obligations to make Development Milestone Payments exceed Fifty-Seven Million U.S. Dollars (US \$57,000,000) in the aggregate with respect to the Product. Each Sales Milestone Payment shall be paid only once on the first achievement of the applicable Sales Milestone Event by Chugai or any of its Affiliates or Sublicensees. In no event shall Chugai's obligations to make Sales Milestone Payments exceed One Hundred Million U.S. Dollars (US \$100,000,000) in the aggregate.
- (c) In the event that the Parties agree that Chugai will Develop and commercialize an Option Product in addition to the Product under this Agreement containing a compound (other than the Compound) that targets an Additional Target (such additional products, "Additional Products"), then the Parties acknowledge and agree that each Development Milestone Payment shall be paid only once on the first achievement of the applicable Development Milestone Event by Chugai or any of its Affiliates or Sublicensees with respect to an Additional Product, regardless of how many times such Milestone Event is achieved with respect to the Additional Product, and in no event shall Chugai's obligations to make Development Milestone Payments exceed Fifty-Seven Million U.S. Dollars (US \$57,000,000) in the aggregate with respect to a particular Additional Product. [*].

(d) [*]

8.3 <u>Royalty Payments</u>. Chugai shall pay Rani the following royalties based on aggregate worldwide annual Net Sales of Product for the relevant Calendar Year during the Royalty Term ("Royalty Payments"). Royalty Payments shall, on a country-by-country basis, commence upon the First Commercial Sale of the Product in such country and payable through [*] (the "Royalty Term"). Upon expiration of the Royalty Term in a country, Chugai shall have a perpetual, non-exclusive, fully paid-up, royalty-free license under the Rani Licensed IP for the Product in the Field in such country, which license shall survive the expiration or any termination of the Agreement.

[*]	[*]
[*]	[*]
[*]	[*]

30

[*]	[*]
[*]	[*]

- 8.4<u>Royalty Reduction</u>. Royalties due to Rani pursuant to Section 8.3 (Royalty Payments) with respect to Net Sales of Product in a country shall be reduced [*] of the amount otherwise payable with respect to such Product if there is no Valid Claim of a Patent Right within Rani's Background IP that Covers the Product in such country.
- 8.5 Peer Product Adjustment. If, during the Royalty Term for a Product in a country and after expiry of the last Valid Claim of the Patent Rights within Rani's Background IP Covering the Product in such country, a Peer Product is sold in such country (after obtaining regulatory approval), then the royalties payable on Net Sales of Product in such country shall be reduced [*] of the amount otherwise payable on such Net Sales pursuant to Section 8.3 (Royalty Payments) in such country. For the sake of clarity, the reduction provided in this Section 8.5 (Peer Product Adjustment) shall be in addition to any reduction provided in Section 8.4 (Royalty Reduction), subject to the provisions of Section 8.6 (Limits).
- 8.6<u>Limits</u>. Notwithstanding the foregoing, in no event shall the total deductions or reductions under Sections 8.4 (Royalty Reduction) and 8.5 (Peer Product Adjustment) in the aggregate reduce the royalties payable to Rani under Section 8.3 (Royalty Payments) with respect to Product in an applicable country in any Calendar Quarter by [*].
- 8.7 Reports. Beginning with the Calendar Quarter in which the First Commercial Sale of Product in the Territory occurs and thereafter for each Calendar Quarter until the expiration of Chugai's obligation to pay royalties with respect to Product hereunder, Royalty Payments and reports of the Net Sales of Product for each Calendar Quarter shall be calculated and delivered by Chugai to Rani under this Agreement within [*] after the end of each such Calendar Quarter for the first three Calendar Quarters of a Calendar Year and within [*] after the end of the Calendar Quarter for the fourth Calendar Quarter of a Calendar Year; *provided, however*, that Chugai shall [*] provide to Rani a good faith estimate of royalties due for a Calendar Quarter within [*] after the end of such Calendar Quarter. [*].
- 8.8<u>Appropriate Measure of Value</u>. Chugai acknowledges that the value provided by Rani hereunder is comprised of many related items, including intellectual property of various types that the royalties set forth in Section 8.3 (Royalty Payments) are intended to capture and access to development and regulatory expertise, manufacturing, data, and other financial and non-financial consideration that the Upfront Payment and Milestone Payments set forth in Sections 8.1 (Upfront Payment) and 8.2 (Milestone Payments) are intended to capture. Therefore, the Parties agree that both the amount and duration of the royalties and other payments set forth in this Article 8 (Payment) are reasonable.

31

- 8.9 <u>Sublicense Payments</u>. Chugai shall be responsible for any license payments, milestone payments and royalty payments owed to a Third Party with respect to the Compound or the approved Indication for the Product, on intellectual property that is licensed by Chugai, its Affiliates or Sublicensees ("*Third Party License Fees*"). Rani shall be responsible for any license payments, milestone payments and royalty payments owed to a Third Party with respect to the Device, on intellectual property that is licensed by Rani or its Affiliates or Chugai, its Affiliates or Sublicensees.
- 8.10<u>Development and Other Costs</u>. [*]. For any given Calendar Quarter, Rani shall invoice Chugai with respect to Rani's External Costs, and Chugai shall pay undisputed invoices within [*] of receipt.
- 8.11 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 check, wire transfer, or electronic funds transfer (EFT) in immediately available funds. Each Party will promptly notify the other Party of the appropriate account information to facilitate any such payments. Regardless of the amounts of any royalties or other payments due under this Agreement or any other agreement between the Parties or their Affiliates, all amounts payable under this Agreement shall be paid in full (subject to Section 8.14 (Taxes)).
- 8.12 Audits. Rani shall keep complete and accurate records pertaining to External Costs reimbursable hereunder in sufficient detail to permit Chugai to reasonably confirm the accuracy of all payments due hereunder. Such records of Rani shall be open (in such form as may be available or reasonably requested by a certified public accountant in accordance with this Section 8.12 (Audits)) to inspection for [*] following the end of the Calendar Year to which they pertain. Chugai shall have the right, at its own expense, to select and have such selected independent, certified public accountant review the records of Rani upon reasonable notice and during regular business hours and under reasonable obligations of confidentiality. The report of such accountant shall be made available to both Parties simultaneously, promptly upon its completion. Chugai'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 [*] audit. Should the inspection lead to the discovery of a discrepancy to Chugai's detriment, then Rani shall promptly pay to Chugai the amount of the discrepancy. Should the inspection lead to the discovery of a discrepancy to the detriment of Rani, then Chugai shall pay to Rani the amount of the discrepancy. Chugai shall pay the full cost of the inspection unless the discrepancy is to the detriment of Chugai and is greater than [*] of the amount actually paid for the audited period, in which case Rani shall pay the cost of such inspection.
- 8.13<u>Currency Conversion</u>. With respect to Net Sales invoiced or expenses incurred in a currency other than U.S. Dollars, such Net Sales invoiced or expenses incurred shall be converted into the U.S. Dollar equivalent using such Party's standard conversion method consistent with the Accounting Standards in a manner consistent

32

with such Party's customary and usual conversion procedures used in preparing its financial statements applied on a consistent basis. Any royalty amount shall be calculated based upon the US Dollar equivalent calculated in accordance with the foregoing.

8.14<u>Taxes</u>.

- (a) Chugai shall be entitled to deduct and withhold from any amounts payable under this Agreement such Taxes as are required to be deducted or withheld therefrom under any provision of Applicable Law. Rani shall provide such information and documentation to Chugai, including as reasonably requested by Chugai, to allow Chugai to determine if any Taxes apply to any payments to be made by Chugai under this Agreement and to establish qualification for a reduced withholding rate or an exemption from Tax under an applicable Tax treaty or other provision of Applicable Law. Rani shall provide Chugai with (A) a U.S. Internal Revenue Service Form 6166 (United States Residency Certification) as received from the United States Internal Revenue Service, and (B) APPLICATION FORM FOR INCOME TAX CONVENTION and ATTACHMENT FORM FOR LIMITATION ON BENEFITS ARTICLE (US) at least [*] prior to any payment hereunder. To the extent that Applicable Law requires that Taxes be withheld with respect to any payments to be made by Chugai to Rani under this Agreement, Chugai shall withhold Taxes from such payment, remit such Taxes to the appropriate tax authority, and furnish Rani with proof of payment of such Taxes. Such withheld amounts shall be treated for all purposes of this Agreement as having been paid to the Person in respect of whom such deduction and withholding was made. If Taxes are so withheld by Chugai and remitted to a tax authority, Chugai shall [*] assist Rani in obtaining a refund or credit of such Taxes to the extent reasonably requested by Rani in writing.
- (b) Notwithstanding anything to the contrary in this Agreement, this Section 8.14(b) (Taxes) shall apply with respect to value-added, sales, goods, services, turnover tax or any similar tax ("Indirect Taxes"). All amounts payable under this Agreement are exclusive of Indirect Taxes. If, under Applicable Law, any Indirect Tax is incurred in connection with amounts payable under this Agreement, any such Indirect Taxes shall be borne by Rani. The Party customarily responsible under Applicable Law shall file all necessary Tax returns and other documentation with respect to all such Indirect Taxes, and the Parties shall reasonably cooperate in duly and properly preparing, executing, and filing any certificates or other documents that may reduce or eliminate any such Indirect Taxes and any such Tax returns and other documentation required to be filed in connection with such Indirect Taxes. The Party responsible for filing any such Tax returns shall provide to the other Party evidence of timely filing and payment of all such applicable Indirect Taxes.

33

8.15<u>Late Payment</u>. 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 8.15 (Late Payment) shall in no way limit any other remedies available to either Party.

8.16 Expiry of Royalty Term. [*].

9. GRANT OF LICENSE

- 9.1 <u>License to Chugai</u>. Effective as of the Effective Date and subject to the terms and conditions of this Agreement, Rani hereby grants to Chugai during the Term an exclusive (even as to Rani, subject to Rani and its Affiliate retaining rights to fulfill Rani's obligations under this Agreement), sublicensable through multiple tiers (subject to Section 9.4 (Sublicensing)), worldwide right and license under the Rani Licensed IP to research, Develop, register, Manufacture, have Manufactured, use, sell, offer for sale, have sold, import, export, commercialize, and market the Product in the Field in the Territory, in each case, in accordance with this Agreement. For the avoidance of doubt, such licenses to Manufacture and have Manufactured Product shall include the right to Manufacture or have Manufactured the Device, subject to the terms and conditions set forth in Section 7.4 (Manufacturing Technology Transfer).
- 9.2 <u>License to Rani</u>. Effective as of the Effective Date and subject to the terms and conditions of this Agreement, Chugai hereby grants to Rani during the Term a non-exclusive, sublicensable (solely in accordance with Section 9.4 (Sublicensing)), worldwide right and license under the Chugai Licensed IP solely to Manufacture and supply the Device and Product to Chugai and to perform its obligations under and in accordance with this Agreement. The licenses under this Section 9.2 (License to Rani) do not include a right to make or have made the Compound.

9.3 Drug Licensee Restrictions.[*].

- 9.4 <u>Sublicensing</u>. Chugai may sublicense, through multiple tiers, the rights and licenses granted to it under Section 9.1 (License to Chugai) and Section 9.6(b) (Licensed Rani Trademark) to its Affiliates and any Third Party, *provided* that Chugai remains primarily responsible for the activities of any such Affiliates and Third Party Sublicensees. Rani may sublicense, through one tier, the rights and licenses granted to it under Section 9.2 (License to Rani) to its Affiliates and any Third Party only with the prior written consent of Chugai, *provided* that Rani remains primarily responsible for the activities of any such Affiliates and Third Party sublicensees.
- 9.5 <u>Subcontracting</u>. Rani may use customary Subcontractors in the performance of activities allocated to it hereunder only with the prior written consent of Chugai. Chugai, its Affiliates and Sublicensees may use customary Subcontractors in the performance of activities allocated to it hereunder without the prior consent of Rani, *provided* that Chugai remains primarily responsible for the activities of any such Subcontractors. Notwithstanding any subcontracting under this Section 9.5

34

(Subcontracting), a Party shall remain responsible hereunder for the full and complete performance of all of such Party's obligations and duties under this Agreement and compliance of any such Subcontractor with the terms of this Agreement. Any use of a Subcontractor 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 Subcontractor undertakes in writing [*] 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.

9.6Trademarks.

- (a) *Product Brand Name*. Chugai shall have the sole right to select a brand name or trademark for the Product and to utilize such brand name or trademark for the commercialization of the Product in the Field in the Territory.
- (b) Licensed Rani Trademark. Chugai, its Affiliates or their Sublicensees may, in its sole discretion, use in connection with commercialization of the Product branding that references the use of a RaniPill Device or Rani's Oral Delivery Technology [*] (a "Licensed Rani Trademark") in a manner mutually agreed by the Parties. Effective as of the Effective Date and subject to the terms and conditions of this Agreement, Rani hereby grants to Chugai during the Term a non-exclusive, sublicensable through multiple tiers (subject to Section 9.4 (Sublicensing)) right and license under the Licensed Rani Trademark solely for use with Product in the Field in the Territory.
- (c) Trademark Quality Standards. If the Licensed Rani Trademark is used, Chugai shall (i) maintain such reasonable quality standards for the Licensed Rani Trademark as it maintains for its own trademarks of a similar nature and shall comply with Rani's reasonable specifications and usage standards supplied to it in writing (and as may be reasonably updated by written notice from time to time): (ii) not use the Licensed Rani Trademark in a manner that suggests any connection with any product other than the Product or any service; and (iii) not use or display the Licensed Rani Trademark in any manner that might dilute, tarnish, disparage or reflect adversely on Rani or such mark. From time to time, upon the reasonable request by Rani, Chugai shall provide examples of the use of the Licensed Rani Trademark in the marketing or promotion of the Product to the extent reasonably practicable and not imposing undue burden on Chugai's operations. Chugai agrees that it shall not seek to register or obtain ownership rights in the Licensed Rani Trademark (or confusingly similar trademark) in the field of prescription pharmaceuticals. For clarity, the foregoing sentence shall not apply to any trademark independently developed and owned by Chugai that does not specifically reference Rani, RaniPill Device or Rani's Oral Delivery Technology.

35

- 9.7<u>Retained Rights</u>. 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 9 (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, Device or Product.
- 9.8<u>Confirmatory Patent License</u>. Rani shall, and shall cause its Affiliates to, if requested to do so by Chugai immediately enter into confirmatory license agreements in such form as may be reasonably requested by Chugai for purposes of recording the licenses granted under Section 9.1 (License to Chugai) with such patent offices in the Territory as Chugai considers appropriate. Until the execution of any such confirmatory licenses, so far as may be legally possible, Rani and Chugai shall have the same rights in respect of the Licensed Rani Patents and Licensed Rani Know-How and be under the same obligations to each other in all respects as if such confirmatory licenses had been executed.
- 9.9 Exclusivity. As of the Effective Date [*], each Party agrees that it shall not, itself or through its Affiliates, directly or indirectly conduct or participate in, or advise, assist, grant any right or license or otherwise enable a Third Party to conduct or participate in, any clinical Development, Manufacturing or commercialization [*].
- 9.10<u>Acquiror IP</u>. If a Party undergoes a Change of Control, the Information and Patent Rights of the acquiring Person and its Affiliates existing prior to the Change of Control shall not be included in the licenses granted by the Parties in this Agreement.

10. INTELLECTUAL PROPERTY

10.1<u>Background IP</u>. 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.

10.2Program Inventions.

- (a) Chugai Program Inventions. Chugai shall solely own Program Inventions that are specifically related to the Compound [*] ("Chugai Program Inventions"). Rani shall, and does hereby, assign all of its rights, title and interests in and to any and all Chugai Program Inventions to Chugai.
- (b) Rani Program Inventions. Rani shall solely own Program Inventions that are specifically related to its Oral Delivery Technology [*] ("Rani Program Inventions"). Chugai shall, and does hereby, assign all of its rights, title and interests in and to any and all Rani Program Inventions to Rani.

36

- (c) Joint Program Inventions. All Program Inventions that are specifically related to the combination of the Device with the Compound [*], and any other Program Inventions which are not Chugai Program Inventions or Rani Program Inventions (collectively, "Joint Program Inventions") shall be jointly owned by the Parties. Neither Party shall assign, transfer, license or otherwise grant any right to a Third Party under the Joint Program Invention (except as expressly permitted under this Agreement) without prior written consent of the other Party, such consent not to be unreasonably withheld or delayed.
- (d) *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 10.2 (Program Inventions) and will execute any and all documents necessary to perfect such assignment. A Program Invention shall be Confidential Information of the Party who owns the Program Invention
- 10.3 Data. Chugai shall solely own Compound-Specific Data, Compound Manufacturing Data, Chugai Device Manufacturing Data, Compound-Related Product Manufacturing Data and Program Data, in each case, subject to the applicable licenses set forth in this Agreement, and the foregoing shall be the Confidential Information of Chugai. Rani shall solely own Device-Related Product Manufacturing Data, Oral Delivery Data and Rani Device Manufacturing Data, in each case, subject to the applicable licenses set forth in this Agreement, and the foregoing shall be the Confidential Information of Rani. Subject to Chugai's prior written consent (which consent shall not be unreasonably withheld, conditioned, or delayed), Chugai shall grant Rani a right of reference to Chugai Device Manufacturing Data, Compound-Related Product Manufacturing Data, and Program Data, in each case to the extent such data are necessary for Rani's Regulatory Activities related to the Device; [*].

10.4Prosecution and Maintenance.

- (a) *Licensed Chugai Patents*. Chugai shall have the sole right to prepare, file, prosecute and maintain the Licensed Chugai Patents on a worldwide basis, at Chugai's own cost and expense.
- (b) Joint Patent Rights. Chugai shall have the first right (but not the obligation) to prepare, file, prosecute and maintain the Joint Patent Rights anywhere in the world, at Chugai's own cost and expense; provided that Chugai keeps Rani reasonably informed of such filing, prosecution, or maintenance of Joint Patent Rights, including by providing Rani with a copy of material filings and communications to and from any applicable patent offices regarding such Joint Patent Rights, and by providing Rani with drafts of any material filings or responses (including copies of the text of the applications) to be made to such patent offices sufficiently in advance of submitting such filings or responses so

37

as to allow for a reasonable opportunity for Rani to review and comment thereon and, prior to filing with the applicable patent offices, will reasonably consider Rani's timely comments in good faith regarding any draft applications, office action responses, or other substantive prosecution matters that relate to the Device or the Oral Delivery Technology as disclosed or claimed in such Joint Patent Rights. If Chugai elects not to continue to prosecute or maintain a given Patent Right within the Joint Patent Rights pursuant to this Section 10.4(b) (Joint Patent Rights), then Chugai will give Rani notice thereof within a reasonable period (but not less than [*]) prior to allowing such Patent Rights to lapse or become abandoned or unenforceable, and thereafter Rani shall have the right, at its cost, to prosecute or maintain such Patent Right included within the Joint Patent Rights, and in such event, Rani shall keep Chugai reasonably informed of such filing, prosecution, or maintenance of such Joint Patent Rights, including by providing Chugai with a copy of material filings and communications to and from any applicable patent offices regarding such Joint Patent Rights, and by providing Chugai with drafts of any material filings or responses (including copies of the text of the applications) to be made to such patent offices sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for Chugai to review and comment thereon, and, prior to filing with the applicable patent offices, will reasonably consider Chugai's timely comments in good faith regarding any draft applications, office action responses, or other substantive prosecution matters.

- (c) Licensed Rani Patents. Rani shall have the first right (but not the obligation) to prepare, file, prosecute and maintain the Licensed Rani Patents (excluding Joint Patent Rights) anywhere in the world, at Rani's own cost and expense. If Rani elects not to continue to prosecute or maintain a given Patent Right within the Licensed Rani Patents pursuant to this Section 10.4(c) (Licensed Rani Patents), then Rani will give Chugai notice thereof within a reasonable period (but not less than [*]) prior to allowing such Patent Rights to lapse or become abandoned or unenforceable, and thereafter Chugai shall have the right, at its cost, to prosecute or maintain such Patent Right included within the Licensed Rani Patents.
- (d) *Cooperation*. During the Term, the Parties agree to cooperate in the prosecution and maintenance of all Patent Rights pursuant to this Section 10.4 (Prosecution and Maintenance).

10.5 Enforcement.

(a) *Notice*. Each Party shall promptly notify in writing the other Party upon becoming aware of any apparent, suspected, threatened or actual infringement, unauthorized use or misappropriation of any Rani Licensed IP or Chugai Licensed IP by a Third Party with respect to a Peer Product anywhere in the world and, in each case, will provide the other Party with all evidence in

38

such Party's possession or control supporting such infringement or unauthorized use or misappropriation.

(b) Chugai Licensed IP. Chugai shall have the sole right to bring any claim, action, suit, arbitration, inquiry, proceeding or investigation by or before any Governmental Authority ("Action") against any Third Party suspected of infringement or misappropriation of Chugai Licensed IP anywhere in the world at its own expense and with counsel of its own choice.

(c) Rani Licensed IP.

- (i) Chugai shall have the first right, but not the obligation, to bring any Action against any Third Party suspected of infringement or misappropriation of Rani Licensed IP (including Joint Program Inventions and Joint Patent Rights) related to a Peer Product anywhere in the world at its own expense and with counsel of its own choice. With respect to such enforcement by Chugai, Chugai shall have the right to deduct from royalties otherwise owed to Rani under Section 8.3 (Royalty Payments) with respect to such Product actual out-of-pocket costs incurred by Chugai to conduct such enforcement. If such Third Party suspected of infringement or misappropriation relates to a Peer Product and Chugai does not bring an Action pursuant to this Section 10.5(c) (Rani Licensed IP) within [*] after receiving written notice from Rani of such suspected infringement or misappropriation, or if earlier, [*] prior to any deadline for bringing such Action under Applicable Law, Rani shall have the right, but not the obligation, to bring an appropriate Action at its own expense and with counsel of its own choice.
- (ii)Rani shall have the sole right to bring any Action against any Third Party suspected of infringement or misappropriation of Rani Licensed IP (but excluding Joint Program Inventions and Joint Patent Rights) related to the Oral Delivery Technology anywhere in the world at its own expense and with counsel of its own choice, so long as such suspected infringement or misappropriation of any Rani Licensed IP (but excluding Joint Program Inventions and Joint Patent Rights) by a Third Party does not relate to a Peer Product.
- (d) Cooperation. Each Party shall reasonably cooperate with the other Party in any Action under Sections 10.5(b) (Chugai Licensed IP) and 10.5(c) (Rani Licensed IP). If required under Applicable Law in order for a Party to initiate or maintain any suit in accordance with this Section 10.5 (Enforcement), the other Party shall join as a party to the suit. The enforcing Party of any action brought under Section 10.5(c) (Rani Licensed IP) shall keep the other Party advised of all material communications, actual and prospective filings, or submissions regarding such action, and shall provide the other Party copies of

and an opportunity to review and comment on any such material communications, filings, and submissions. The non-enforcing Party under any Action brought pursuant to Section 10.5(c)(i) shall have a right to participate in such enforcement, and the enforcing Party shall seek and reasonably consider the non-enforcing Party's comments before determining the enforcement strategy.

10.6Defense.

- (a) *Notice*. Each Party will promptly notify the other Party if a Third Party brings any Action alleging that Rani or Chugai or any of their respective Affiliates or (sub)licensees are infringing, misappropriating or otherwise violating such Third Party's intellectual property rights with respect to the manufacture, use, sale, offer for sale, importation or exploitation of Product (any such Action, each, a "*Product Infringement Claim*").
- (b) Compound Claims. If a Product Infringement Claim relates to the Compound only and not the Oral Delivery Technology (a "Compound Claim"), then Chugai shall have the sole right to manage the defense and settlement of such claim anywhere in the world. Chugai shall keep Rani reasonably informed regarding the handling of the claim, to the extent reasonably relevant to Product. Neither Party shall be obligated to share with the other Party regarding such claim any information regarding matters outside the scope of the Collaboration. Chugai shall be responsible for paying any award, judgement or settlement payments related to Compound Claims.
- (c) Product Infringement Claim other than Compound Claim. Chugai shall have the first right, but not the obligation, to defend against any Product Infringement Claim other than Compound Claim anywhere in the world, at its own cost. If Chugai intends not to defend, and take other actions with respect to such claim of Product Infringement Claim other than Compound Claim, it shall notify Rani of such intent within [*]. In such event, Rani shall have the right to do so, at its cost. Each Party shall reasonably cooperate with the other in any such litigation or defense of such claims. Unless otherwise agreed by the Parties, the Party defending the Product Infringement Claim under this Section 10.6(c) (Product Infringement Claim other than Compound Claim) shall be responsible for paying any award, judgement or settlement payments related to such claims. [*].
- (d) Cooperation. The Parties shall keep each other advised of all material communications, actual and prospective filings or submissions regarding such claims, and will consult with each other and provide each other opportunity to review and comment on any such communications, filings and submissions. The Party controlling the defense will have the right to settle such Product Infringement Claim on terms deemed reasonably appropriate by such

40

Party; provided that, unless any such settlement includes a full and unconditional release from all liability of the other Party and does not adversely affect the rights or interests of such other Party, any such settlement will be subject to the other Party's prior written consent.

10.7Third Party IP.

- (a) Third Party IP Infringement. Neither Party shall 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 Collaboration activities), or otherwise resolve such potential infringement, which the Parties shall use good faith, [*] to do.
- (b) Freedom-to-Operate License. Chugai, its Affiliates or Sublicensees shall have the right to obtain a freedom-to-operate license from a Third Party, if Chugai, its Affiliates or Sublicensees reasonably determine that it is necessary to obtain such license for the manufacture, use, sale, offer for sale, importation or exploitation of Product. [*].
- 10.8<u>Allocation of Recoveries</u>. All Recoveries from actions brought under Section 10.5 (Enforcement) with respect to Rani Licensed IP enforced against a Peer Product in the Territory shall first go to reimburse the Parties for any costs incurred with respect to such enforcement action [*].
- 10.9Employee Agreements. Prior to beginning work relating to any aspect of the subject matter of this Agreement (including being given access to Rani Licensed IP or Chugai Licensed IP, as applicable, 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 a confidentiality agreement and an invention assignment agreement, or (ii) otherwise agreed to be bound by written obligations of (a) non-disclosure and non-use of Confidential Information, and (b) assignment of all of his or her right, title and interest in and to any intellectual property to such Party, in each case of (i) and (ii), pursuant to which each such person agrees to comply with all of the obligations of the Party that are at least as restrictive as those contained in this Agreement. It is understood and agreed that any such non-disclosure, non-use 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.
- 10.10<u>Patent Challenge</u>. If (i) Chugai or its Affiliates contests or assists a Third Party in contesting the validity or enforceability of any Licensed Rani Patents (but excluding the Joint Patent Rights) that is owned by Rani as of the date of such contest, in any court action or governmental proceeding, other than as may be necessary or

41

reasonably required to assert a defense, cross-claim, or counter-claim in an infringement action or proceeding with respect to the challenged Licensed Rani Patents asserted by Rani, its Affiliates or their licensees or assignees against Chugai, its Affiliates or Sublicensees, or to respond to a court request or order or administrative agency request or order, (each such challenge, a "Patent Challenge") or (ii) any of Chugai's Sublicensee participates in a Patent Challenge and Chugai does not terminate its sublicense with such Sublicensee following written notice from Rani, Rani shall have the right to terminate this Agreement upon [*] written notice unless Chugai or its Affiliates or its Sublicensee has either filed a motion to dismiss with prejudice such Patent Challenge or to otherwise terminate such Patent Challenge, or caused such Patent Challenge to be dismissed with prejudice or terminated, in either case as soon as possible, and in no event later than [*] following receipt of such notice. For clarity, if Chugai terminates the sublicense with a Sublicensee who participated in a Patent Challenge withing [*] of receiving written notice from Rani of such Sublicensee Patent Challenge, Rani shall not be permitted to terminate this Agreement even if such Sublicensee continues with the Patent Challenge. Notwithstanding the foregoing, none of the following activities shall be a Patent Challenge and Rani shall not have a right to terminate this Agreement with respect to any Patent Challenge undertaken by an Affiliate of Chugai that becomes such an Affiliate as a result of an acquisition and where such new Affiliate was participating in the Patent Challenge prior to such acquisition and in the case Chugai is the acquiror, require such new Affiliate to [*] initiate proceedings to terminate such Patent Challenge within [*] after the consummation of such acquisition. For clarity, this Section 10.10 (Patent Challenge) shall not apply to arguments made by Chugai, its Affiliates or Sublicensees that distinguish the inventions claimed in any Licensed Rani Patents from those claimed in the patents or patent applications controlled by Chugai or its Affiliates or Sublicensees.

11. COMPOUND REPLACEMENT OPTION

- 11.1Replacement Option Grant. Chugai shall have a one-time option (the "Replacement Option") to replace the original licensed Compound ("Original Compound") with a different compound (the "Replacement Compound"), subject to the terms and conditions of this Article 11 (Compound Replacement Option). For clarity, for purposes of this Article 11 (Compound Replacement Option), "compound" shall be interpreted consistent with Section 1.31 to include any amino acid sequence selected by Chugai during the Term and any backups and analogs thereof, and changes among such amino acid sequences, backups, or analogs shall be treated as the same compound under this Article 11 (Compound Replacement Option). [*].
- 11.2<u>Replacement Option Period</u>. The Replacement Option shall be exercisable by Chugai during the period from the Effective Date through the date that is [*] (the "Replacement Option Period") [*].
- 11.3<u>Replacement Option Exercise Notice</u>. Chugai may exercise the Replacement Option by providing written notice to Rani at any time during the

42

Replacement Option Period (the "Replacement Option Exercise Notice"). Upon providing Replacement Option Exercise Notice, Chugai shall submit to Rani a detailed written request identifying the proposed Replacement Compound. The date that Rani receives the Replacement Option Exercise Notice shall be the effective date of the replacement ("Replacement Effective Date").

- 11.4<u>Scope and Limitation</u>. The Replacement Compound must [*]. For clarity, for purposes of determining compliance with this Section 11.4 (Scope and Limitations), changes among amino acid sequences, backups, or analogs of the Replacement Compound shall be treated as the same compound.
- 11.5 Effect of Replacement. On or after the Replacement Effective Date (i) all references to the "Compound" in this Agreement shall be deemed to refer to the Replacement Compound, [*] (iv) Rani will be eligible to receive any of the Milestone Payments set forth in Section 8.2 (Milestone Payments) that were not previously paid with respect to Development of Product containing the Original Compound. For clarity, Chugai is not obligated to pay any Milestone Payments set forth in Section 8.2 (Milestone Payments) with respect to Product containing the Replacement Compound to the extent such Milestone Payments were already paid with respect to Product containing the Original Compound. Further, changes among amino acid sequences, backups, or analogs of the Replacement Compound shall not, solely due to such changes, be treated as a new compound and re-trigger any Milestone Payments under this Section 11.5 (Effect of Replacement).
- 11.6 Ownership and Use of Data and IP Related to Original Compound. On or after the Replacement Effective Date, the following terms shall apply.
 - (a) Ownership of Prior Results. All data, results, and intellectual property (including any Patent Rights, Information, and Regulatory Filings) generated by or on behalf of either Party, or jointly between the Parties, prior to the Replacement Effective Date, shall remain the property of the respective Parties, subject to the license rights granted under this Agreement and all such data, results, and intellectual property shall remain subject to the confidentiality obligations of this Agreement.
 - (b) Use of Prior Results. The Parties may continue to use any general Information, data, or Program Inventions developed during work on the Original Compound that is applicable to the Replacement Compound, provided that such use does not violate any Third Party rights or the terms of this Agreement.
 - (c) *Patent Filings*. Each Party shall promptly notify the other of any Program Inventions generated with respect to the Original Compound prior to the Replacement Effective Date. Ownership of such Program Inventions shall be determined in accordance with the terms set forth in Section 10.2 (Program Inventions), and the prosecution and maintenance of any resulting Patent Rights

43

shall be done in accordance with the terms set forth in Section 10.4 (Prosecution and Maintenance). The Parties shall discuss in good faith whether such Program Inventions may be assigned, licensed, or otherwise used in relation to the Replacement Compound, if applicable.

- (d) Regulatory Filings. If Chugai has made any regulatory filings with respect to the Original Compound, such filings shall remain the property of Chugai. Rani shall have the right of reference to or access to (at Chugai's sole discretion) such regulatory filings, in each case to the extent any data in such regulatory filings are necessary for Rani's Regulatory Activities with respect to the Device, subject to any regulatory requirements, confidentiality, or Third Party restrictions.
- 11.7<u>Limitation</u>. For clarity, the rights granted in this Article 11 (Compound Replacement Option) will apply to any Option Product under Article 13 (Option Rights with Respect to Additional Targets).

12. FIRST REFUSAL RIGHTS WITH RESPECT TO ADDITIONAL TARGETS

12.1 First Refusal Right. During a period from the effective date of this Agreement through [*] (the "Additional Rights Period"), if Rani receives a bona fide offer or term sheet from a Third Party that Rani is willing to accept to grant a nonexclusive or exclusive license for any product consisting of the Device containing a compound that targets any Additional Target ("ROFR Product"), on an Additional Target-by-Additional Target basis, Rani shall promptly notify Chugai in writing [*] ("Offer Notice"). Chugai will have [*] upon its receipt of the Offer Notice ("Exercise Period") to determine whether it wishes to exercise its rights under Section 12.2 (Negotiation of License to ROFR Product) to exclusively negotiate a non-exclusive or exclusive license to develop, manufacture, and commercialize the ROFR Product by providing Rani a written notice indicating its intent to negotiate such license ("Exercise Notice") [*]. In addition, for purposes of this Article 12 (First Refusal Rights with Respect to Additional Targets), "compound" shall be interpreted consistent with Section 1.31 to include any amino acid sequence selected by Chugai during the Term and any backups and analogs thereof, and changes among such amino acid sequences, backups or analogs shall be treated as the same compound for the applicable Additional Target.

12.2Negotiation of License to ROFR Product. If Chugai provides Rani with an Exercise Notice within the Exercise Period, then Rani shall provide Chugai with such Third Party bona fide offer or term sheet and Rani agrees to exclusively negotiate in good faith a definitive license agreement with Chugai for the ROFR Product for [*] after receiving the Exercise Notice, subject to additional extensions as mutually agreed to by the Parties (the "Negotiation Period"). The definitive license agreement for the ROFR Product shall include [*] (ii) development milestone payments, sales milestone payments, and royalty payments to be negotiated between the Parties based on the bona fide offer or term sheet received from the Third Party; provided that the negotiated

44

aggregate U.S. Dollar amount of milestone and royalty payments for the ROFR Product is substantially the same as, or higher than, the aggregate U.S. Dollar amount of milestone and royalty payments presented in the bona fide offer or term sheet from the Third Party. [*], for purposes of this Article 12 (First Refusal Rights with Respect to Additional Targets), changes among amino acid sequences, backups, or analogs of the compound targeting the same Additional Target shall be treated as the same compound and shall not, solely due to such changes, trigger duplicate milestone or royalty obligations for the same Additional Target.

12.3 Reinstatement of First Refusal Right. If Chugai fails to provide Rani the Exercise Notice within the Exercise Period or if Chugai and Rani are unable to negotiate a definitive license agreement on mutually agreed terms within the Negotiation Period, then Rani shall be free to negotiate with the Third Party a license with respect to the Additional Target described in the Offer Notice; [*] (b) if Rani does not enter into a definitive agreement with such Third Party within [*], Chugai's rights pursuant to Section 12.2 (Negotiation for a License to ROFR Product) shall be reinstated on an Additional Target-by-Additional Target basis for the remainder of the Additional Rights Period and Rani shall notify Chugai thereof.

13. OPTION RIGHTS WITH RESPECT TO ADDITIONAL TARGETS

13.1 Option Right. Without limitation to the foregoing, if, during the Additional Rights Period, Chugai desires to obtain a non-exclusive or exclusive license for any product consisting of the Device containing a compound that targets any Additional Target ("Option Product"), on an Additional Target-by-Additional Target basis, Chugai shall notify Rani of its desire in writing (which notice will identify the Additional Target) that it wishes to receive a non-exclusive or exclusive license to develop, manufacture, and commercialize the Option Product ("Option Notice"). Chugai shall have such option right for up to five (5) Additional Targets of Chugai's choosing. Rani shall invoice Chugai with respect to the Additional Target Fee within [*] of receipt of the Option Notice, and Chugai shall pay the Additional Target Fee within [*] of receipt of the invoice from Rani. For clarity, the Additional Target Fee is payable on an Additional Target-by-Additional Target basis and is not compound-specific; no additional Additional Target Fee will be payable for any subsequent change of the compound targeting the same Additional Target, subject to Article 11 (Compound Replacement Option). [*]. In addition, for purposes of this Article 13 (Option Rights with respect to Additional Targets), "compound" shall be interpreted consistent with Section 1.31 to include any amino acid sequence selected by Chugai during the Term and any backups and analogs thereof, and changes among such amino acid sequences, backups, or analogs shall be treated as the same compound for the applicable Additional Target and shall not trigger an additional Additional Target Fee and shall not constitute a replacement under Article 11 (Compound Replacement Option).

13.2<u>Grant of License to Option Product</u>. If Chugai provides Rani with an Option Notice and pays Rani the Additional Target Fee pursuant to Section 13.1

45

(Option Right), then the license granted to Chugai under this Agreement shall be automatically extended to the Option Product for each Additional Target. On or after the payment of the Additional Target Fee by Chugai, (i) all references to the "Product" in this Agreement shall be deemed to include the Option Product, (ii) all references to the "Compound" in this Agreement shall be deemed to include a compound that targets any Additional Target and is contained in the Option Product, unless otherwise agreed in writing, (iii) the Parties agree to negotiate in good faith a new scope of exclusivity as set forth in Section 9.9 (Exclusivity) relating to such compound contained in the Option Product, and (iv) Rani will be eligible to receive the same aggregate Dollar amount of Milestone Payments set forth in Section 8.2 (Milestone Payments) for the first achievement of the corresponding Milestone Event by the Option Product, on an Additional Target-by-Additional Target basis, [*]. For clarity, all milestone payment obligations under Section 8.2 (Milestone Payments) with respect to an Additional Target will be determined on an Additional Target-by-Additional Target basis and will not be triggered more than once for the same Additional Target due solely to a change in the compound that targets such Additional Target. Further, for purposes of this Article 13 (Option Rights with respect to Additional Targets), changes among amino acid sequences, backups, or analogs of the compound targeting the same Additional Target shall be treated as the same compound and shall not, solely due to such changes, trigger additional Milestone Payments for the same Milestone Event for that Additional Target.

13.3 <u>Termination of Option Right</u>. Chugai's option right pursuant to Section 13.1 (Option Right) shall terminate at the earlier of (i) the day Chugai executes a license agreement with Rani for a fifth (5th) Additional Target, or (ii) the expiration of the Additional Rights Period.

14. CONFIDENTIALITY AND PUBLICATIONS

14.1 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 Party receiving any Confidential Information (the "Receiving Party") furnished to it by the other Party (the "Disclosing Party") pursuant to this Agreement shall, and shall cause its officers, directors, employees, and agents to, keep such Confidential Information confidential and shall not publish or otherwise disclose or use such Confidential Information, directly or indirectly, for any purpose other than as provided for in this Agreement. For clarity, any information provided by Rani under Article 18 ([*]), including any [*], and related analyses, will be deemed Confidential Information of Rani, and Chugai may use such information solely to the extent [*] for [*] in connection with this Agreement. Notwithstanding the foregoing, Confidential Information constituting Regulatory Filings owned by Chugai pursuant to Article 5 (Regulatory), Program Data, Compound-Related Product Manufacturing Data, Chugai Device Manufacturing Data, and any other Information developed, owned, or Controlled by Rani or any of its Affiliates (including Licensed Rani Know-How) relating exclusively to the Compound or the Product or the exploitation of any of the

46

foregoing in the Field in the Territory shall be deemed the Confidential Information of Chugai (and Chugai shall be deemed the Disclosing Party and Rani shall be deemed the Receiving Party with respect thereto). Notwithstanding the foregoing, Confidential Information shall not include any information to the extent that it can be established by competent written documentation by the Receiving Party that such information:

- (a) 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;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;
- (c) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party and other than through any act or omission of the Receiving Party in breach of this Agreement; or
- (d) was independently developed by the Receiving Party (without reference to or use of Confidential Information of the Disclosing Party) as demonstrated by documented evidence prepared contemporaneously with such independent development.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

14.2<u>Authorized Disclosure</u>. Except as prohibited in this Agreement, each Party may disclose Confidential Information of the other Party solely as follows: (i) to the extent such disclosure is to a Governmental Authority as [*] in filing or prosecuting patent, copyright and trademark applications in accordance with 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 Product, or otherwise as 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 give reasonable advance written notice to the other Party of such disclosure requirement and, shall [*] secure confidential treatment of such Confidential Information required to be disclosed and compulsory disclosures of such Confidential Information made pursuant to this Section 14.2

47

(Authorized Disclosures) shall not relieve the Receiving Party of its obligations of confidentiality and non-use with respect to such Confidential Information; (ii) to Receiving Party's, directors, officers, employees, Affiliates, consultants, independent contractors (including Subcontractors), Sublicensees, potential Sublicensees, agents or advisors (including without limitation attorneys, accountants, bankers, financial advisors and members of advisory boards) (collectively, "Representatives") having a need to know such information for the purposes permitted under this Agreement (including, for Chugai, [*] under Article 18 ([*]) and who have signed, prior to the disclosure of Confidential Information to such Representative, confidentiality agreements or are otherwise bound by confidentiality obligations at least as restrictive as those contained herein; provided, however, that the Receiving Party shall be responsible for the breach of this Agreement by its Representatives as if such breach were by the Receiving Party itself; (iii) subject to Section 20.3 (Change of Control), to its actual and bona fide potential investors, lenders or other financing sources, acquirors, and licensees 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 [*] 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 (iii) shall not apply to and shall not permit the disclosure of Program Data, Compound-Specific Data, Compound Manufacturing Data, Compound-Related Product Manufacturing Data, Compound-specific Information [*], Chugai Device Manufacturing Data, or Additional Targets by Rani, unless Rani receives the prior written consent of Chugai, or Rani Device Manufacturing Data, Device-Related Product Manufacturing Data, or Device-specific Information [*] by Chugai, unless Chugai receives the prior written consent of Rani); (iv) with respect to Chugai, [*], to the extent necessary for their consolidated accounting and audit process or other similar financial or accounting matters; or (v) to the extent mutually agreed to by the Parties.

14.3 Notification. The Receiving Party shall notify the Disclosing Party promptly upon discovery of any unauthorized use or disclosure of the Disclosing Party's Confidential Information, and shall cooperate with the Disclosing Party in any reasonably requested fashion to assist the Disclosing Party to regain possession of such Confidential Information and to prevent its further unauthorized use or disclosure.

14.4Publications and Presentations.

(a) *Publication and Presentation Process*. Chugai shall have the right and responsibility to publish and publicly present Program Data or other key results achieved with respect to Product in the Collaboration. Rani shall only have the right to publish or publicly present Program Data or other key results achieved with respect to Product with Chugai's prior written consent, provided that, once Chugai publishes or publicly presents Program Data or other key results achieved with respect to Product in the Collaboration, then Rani shall have the right to repeat such data or results without consent of Chugai.

48

(b) *Non-Program Data*. Subject to the confidentiality provisions in this Agreement, Rani shall have the right to publicly disclose, publish and/or present Oral Delivery Data that is unrelated to the Compound or Product without requiring prior consent of the other Party.

14.5 Terms and Conditions Confidential; Use of Name. Neither Party will disclose the terms and conditions of this Agreement except as may be required by Applicable Law. 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. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 14.5 (Terms and Conditions Confidential; Use of Name) shall not prohibit either Party from making any disclosure identifying the other Party in Regulatory Filings or communications with Governmental Authorities or that, in the opinion of the Disclosing Party's counsel, is otherwise required by Applicable Law; provided that such Party shall submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable (and in no event less than [*] prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon.

14.6<u>Prior Agreement</u>. This Agreement supersedes [*] (the "*Prior Agreement*"), with respect to information disclosed thereunder [*]. All confidential information exchanged between the Parties under the Prior Agreement shall be deemed Confidential Information of the Disclosing Party hereunder and shall be subject to the terms of this Agreement.

14.7 <u>Attorney-Client Privilege</u>. 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.

14.8<u>Survival</u>. The obligations and prohibitions contained in this Article 14 (Confidentiality and Publications) as they apply to Confidential Information will survive any expiration or termination of this Agreement for a period of [*].

49

15. Representations, Warranties and Covenants

- 15.1 <u>Mutual Representations and Warranties</u>. Each of the Parties hereby represents and warrants to the other Party as of the Effective Date as follows:
 - (a) It is duly organized and validly existing under the Applicable Law of its jurisdiction of incorporation 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;
 - (b) 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 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 action;
 - (c) To its knowledge, 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 of 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; and
 - (d) It has not been Debarred or the subject of Debarment proceedings.
- 15.2<u>Rani Representations and Warranties</u>. Rani hereby represents, warrants and covenants that:
 - (a) The Licensed Rani Patents (i) in existence as of the Effective Date are listed on Exhibit 15.2(a), (ii) are, to Rani's knowledge, subsisting and are not invalid or unenforceable, in whole or in part, (iii) are being diligently prosecuted and maintained in the patent office in which each such Licensed Rani Patent is then-pending or granted in accordance with Applicable Law, and (iv) have been filed and maintained in accordance with applicable patent law and all applicable fees have been paid on or before the due date for payment;
 - (b) As of the Effective Date, Rani owns or otherwise Controls all of the rights, title and interest in and to the Licensed Rani Patents, and has the right to grant to Chugai the rights therein purported to be granted to Chugai under this Agreement;

50

- (c) The Development, Manufacture, or commercialization of the Device as contemplated herein will not be subject to any other license or agreement, to which Rani or any of its Affiliates is a party, that would prevent or materially adversely affect (i) Rani's and/or Chugai's ability to conduct the contemplated activities of the Collaboration in accordance with this Agreement, or (ii) the rights granted to Chugai hereunder;
- (d) Rani has obtained the right (including under any Patent Rights, trademark rights and other intellectual property rights) to use (including grant Chugai access to use) all Information and all other materials (including any manufacturing processes and procedures) developed or delivered by any Third Party under any agreements between Rani and any such Third Party with respect to the Device and Oral Delivery Technology;
- (e) As of the Effective Date, 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 the Device misappropriates or infringes the rights of such Third Party;
- (f) The Licensed Rani Patents represent all Patent Rights owned, inlicensed or held for use by Rani or its Affiliates that are [*] to exploit the Device and there is no Information owned or in-licensed or held for use by Rani or any of its Affiliates that is [*] to exploit the Device that is not Licensed Rani Know-How;
- (g) To Rani's knowledge, the conception, development, and reduction to practice of the Licensed Rani Patents and Licensed Rani Know-How, have not constituted or involved the misappropriation of trade secrets or other rights or property of any Person;
- (h) Neither Rani nor any of its Affiliates has entered, and during the Term will not enter, into any agreement, whether written or oral, with respect to, or otherwise assigned, transferred, licensed, conveyed or encumbered its right, title, and interest in or to any Patent Rights or other intellectual property or proprietary right or Information that are related to the use of the Device for the treatment of hemophilia [*] that would (i) prevent or materially adversely affect Rani or Chugai from performing its contemplated activities in the Development, Manufacture, or commercialization of the Device or Product in accordance with this Agreement, or (ii) otherwise conflict with the rights granted to Chugai hereunder;
- (i) All current and former officers, employees, agents and consultants of Rani or any of its Affiliates who are inventors of or have otherwise materially contributed to the creation or development of any Licensed Rani Patent or Licensed Rani Know-How have executed and delivered to Rani or such

51

Affiliate an assignment or other agreement regarding the protection of proprietary information and the assignment to Rani or such Affiliate of any Licensed Rani Patent and Licensed Rani Know-How, the current form of which has been made available for review by Chugai. To Rani's knowledge, no current officer, employee, agent or consultant of Rani or any of its Affiliates is in violation of any term of any assignment or other agreement regarding the protection of Patent Rights or other intellectual property or proprietary Information of Rani or such Affiliate or of any employment contract or any other contractual obligation relating to the relationship of any such Person with Rani;

- (j) The Licensed Rani Know-How has been kept confidential by Rani or has been disclosed to Third Parties only under terms of confidentiality. To Rani's knowledge no breach of such confidentiality has been committed by any Person:
- (k) The inventions claimed by the Licensed Rani Patents as of the Effective Date (i) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof or any state government or any agency thereof, (ii) are not a "subject invention" as that term is described in 35 U.S.C. § 201(e), (iii) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. part 401 and (iv) are not the subject of any licenses, options or other rights of any other Governmental Authority, within or outside the United States, due to such Governmental Authority's funding of research and development or otherwise (other than the right to receive payments or any law of general application that applies to personal property generally, e.g., takings laws);
- (1) Rani and its Affiliates have conducted, and their respective contractors and consultants have conducted, all Development of the Device and the Oral Delivery Technology in accordance with Applicable Law, including GMP and GLP;
- (m)To Rani's knowledge, the research, Development, Manufacture, sale, offer for sale, import or export of the Device does not infringe a Valid Claim of the Patent Rights, or misappropriate any other intellectual property rights, of any Third Party in the Territory;
- (n) Neither Rani nor any of its Affiliates, nor any of its or their respective officers, employees, or agents has made or will make, or will cause Chugai to make, an untrue statement of material fact or fraudulent statement to the FDA or any other Governmental Authority with respect to the Development

52

of the Device or the Product, failed or will fail to disclose, or cause Chugai to fail to disclose, a material fact required to be disclosed to the FDA or any other Governmental Authority with respect to the Development of the Device or the Product, or committed or will commit an act, made or make a statement, or failed or fail to make a statement, or cause Chugai to commit an act, make a statement, or fail to make a statement, with respect to the Development of the Device or the Product that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory; and

- (o) In developing the Device, Rani has not used any employee or contractor who is or has been Debarred or is or has been the subject of Debarment proceedings and neither Rani nor its Affiliates nor any of their respective officers, employees or agents have made an untrue statement of material fact or fraudulent statement to the FDA or any other Governmental Authority with respect to the Device and the Oral Delivery Technology, failed to disclose a material fact required to be disclosed to the FDA or any other Governmental Authority with respect to the Device and the Oral Delivery Technology, or committed an act, made a statement or failed to make a statement with respect to the Development of the Device and the Oral Delivery Technology that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory.
- 15.3 <u>Chugai Representations and Warranties</u>. Chugai hereby represents, warrants and covenants that:
 - (a) As of the Effective Date, Chugai owns or otherwise Controls all of the rights, title and interest in and to the Licensed Chugai Patents and has the right to grant to Rani the rights therein purported to be granted to Rani under this Agreement;
 - (b) As of the Effective Date, Chugai has not received any written communication from any Third Party (i) challenging the validity of Licensed Chugai Patents or the effectiveness or ownership of Chugai Licensed IP, or (ii) asserting or alleging that the development, manufacture, use or sale of any Compound misappropriates or infringes the rights of such Third Party;
 - (c) As of the Effective Date, Chugai has not received any written notice that a Governmental Authority (i) does not, or intends not to, approve the regulatory filing of any Compound for marketing, or (ii) has initiated, or intends

53

to initiate, any investigation or action to withdraw any regulatory filing or regulatory approval with respect to the development, manufacture or commercialization of any Compound;

- (d) To Chugai's knowledge, the research, development, manufacture, sale, offer to sell, import or export of the Compounds as they exist 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, other than Patent Rights for which Chugai has a valid license that covers the proposed activities of this Collaboration; and
- (e) In developing the Compounds, Chugai has not used any employee or contractor who is or has been Debarred or is or has been the subject of Debarment proceedings and neither Chugai nor its Affiliates nor any of their respective officers, employees or agents have made an untrue statement of material fact or fraudulent statement to the FDA or any other Governmental Authority with respect to the Compounds, failed to disclose a material fact required to be disclosed to the FDA or any other Governmental Authority with respect to the Compounds, or committed an act, made a statement or failed to make a statement with respect to the development of the Compounds that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory.
- 15.4Disclaimer of Warranties. EXCEPT AS SET FORTH IN THIS ARTICLE 15 (REPRESENTATIONS, WARRANTIES AND COVENANTS), CHUGAI AND RANI EXPRESSLY DISCLAIM ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE COLLABORATION, COMPOUNDS, DEVICE, PRODUCT, ORAL DELIVERY TECHNOLOGY, RANI LICENSED IP, CHUGAI LICENSED IP, THIS AGREEMENT, OR ANY OTHER SUBJECT MATTER RELATING TO THIS AGREEMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR NONINFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.
- $15.5 \underline{\text{Covenants}}$. Each of the Parties hereby covenants to the other Party as follows:
 - (a) It shall not knowingly use in connection with the Development and Manufacture to take place pursuant to this Agreement any employee, consultant or investigator that has been Debarred or the subject of Debarment proceedings;
 - (b) It shall carry out its activities hereunder in compliance with Applicable Law (including Applicable Law relating to economic sanctions, bribery, and data privacy); and

54

(c) 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

(d) It shall not grant or otherwise transfer any right to any Third Party that conflicts with the rights granted to the other Party hereunder.

16. LIMITATIONS OF LIABILITY; INSURANCE

16.1 Limitations of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, SPECIAL, INCIDENTAL, EXEMPLARY, PUNITIVE 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 16.1 (Limitations of Liability) shall not apply with respect to (i) either Party's indemnification obligations under Article 17 (Indemnification), (ii) Sections 14.1 (Confidentiality; Exceptions) or 14.2 (Authorized Disclosure), or (iii) gross negligence or willful misconduct of a Party.

5.5

16.2<u>Insurance</u>. 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, solely with respect to Chugai, reasonable self-insurance sufficient to provide materially the same level and type of protection). Without limiting the foregoing, at least [*] prior to the initiation of any clinical trial by or on behalf of Chugai or its Affiliates or their Sublicensees, Rani shall at its own expense procure and maintain during the Term (and for [*] thereafter) clinical trial liability insurance coverage adequate to cover its obligations hereunder and which is/are consistent with normal business practices of prudent biotechnology or pharmaceutical companies engaged in clinical trials of products at the same stage conducted by Chugai. Additionally, at least [*] prior to First Commercial Sale, Rani shall at its own expense procure and maintain during the Term (and for [*] thereafter) product liability insurance coverage adequate to cover its obligations hereunder and which is consistent with normal business practices of prudent pharmaceutical companies. Such insurance shall not be construed to create a limit of Rani's liability with respect to its indemnification obligations under this Agreement. Rani will name Chugai as an additional insured party under such insurance policy, and shall provide Chugai with written notice at least [*] prior to the cancellation, nonrenewal or a material change in such insurance. Rani shall provide Chugai with a certificate of insurance to evidence Rani's product liability insurance or other evidence of such insurance, upon request.

17. Indemnification

17.1 Indemnity.

(a) Indemnification by Chugai. Chugai 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 Chugai's cost and expense, from and against any and all liabilities, losses, costs, damages, fees or expenses (including reasonable legal expenses and attorneys' fees incurred by any Rani Indemnitees) (collectively, "Losses") arising out of any Third Party 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 negligence or willful misconduct of Chugai, its Affiliates or agents in performing under this Agreement, (ii) a breach by Chugai of this Agreement, including any of Chugai's representations, warranties or covenants in this Agreement, or (iii) Chugai's, its Affiliate's or its Sublicensee's Development, Manufacture or commercialization of any Compound, Device or Product, including product liability related to any Compound; except, in each case, excluding such Losses to the extent they arise from clauses (i), (ii) or (iii) of Section 17.1(b) (Indemnification by Rani).

56

(b) Indemnification by Rani. Rani shall defend, indemnify, and hold harmless Chugai, its Affiliates, and their respective directors, officers, employees and agents (solely to the extent acting within their agency) (collectively, "Chugai Indemnitees"), at Rani's cost and expense, from and against any and all Losses (including reasonable legal expenses and attorneys' fees incurred by any Chugai Indemnitees) arising out of any Claim brought against any Chugai Indemnitee by a Third Party to the extent such Losses result from (i) the negligence or willful misconduct of Rani, or its Affiliates or agents in performing under this Agreement, (ii) a breach by Rani of this Agreement, including any of Rani's representations, warranties or covenants in this Agreement, (iii) the infringement of the intellectual property or other proprietary rights of any Third Party from Chugai's or any of its Affiliates or their Sublicensees' use of the Rani name or Licensed Rani Trademark, or (iv) Rani's, its Affiliate's or its Subcontractor's Development or Manufacture of any Device or Product, including product liability related to any Device; but, in each case, excluding such Losses to the extent they arise from clauses (i), (ii), or (iii) of Section 17.1(a) (Indemnification by Chugai).

17.2Claim for Indemnification. Whenever any Claim or Loss shall arise for which a Chugai Indemnitee or a Rani Indemnitee (the "Indemnified Party") may seek indemnification under this Article 17 (Indemnification), the Indemnified Party 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 17.2 (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 17.2 (Claim for Indemnification), 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 Indemnifying Party shall act diligently and in good faith with respect to all matters relating to the settlement or disposition of any Claim as the settlement or disposition relates to the Indemnified Party and shall cause such defense to be conducted by counsel reasonably acceptable to the Indemnified Party. 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 material breach of its obligation to defend hereunder. In no event shall the Indemnifying Party settle any Claim without the prior written consent of the Indemnified 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 Indemnified Party, or includes any admission of wrongdoing or that any intellectual property or proprietary right of the Indemnified Party is invalid

57

or unenforceable. The Indemnified Party shall reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense.

18. [*]

19. TERM AND TERMINATION

19.1<u>Term</u>. This Agreement shall come into effect as of the Effective Date and, unless terminated pursuant to this Article 19 (Term and Termination), shall remain in effect until it expires (a) on a country-by-country basis, upon the expiration of the Royalty Term in such country and (b) in its entirety, upon the expiration of all Royalty Terms in all countries in the Territory (the "*Term*").

- 19.2 Termination. This Agreement may be terminated as follows:
- (a) Mutual Agreement. The Parties may terminate the Agreement at any time upon mutual written agreement.
- (b) Convenience. Chugai shall have the right to terminate this Agreement at will, in its sole discretion, on not less than [*] prior written notice to Rani.
- (c) 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 any undisputed amounts due hereunder), then the other Party shall be permitted to terminate this Agreement by written notice given within [*] after the end of such cure period and effective upon delivery.
- (d) Force Majeure. A Party has the right to terminate this Agreement as set forth in Section 20.8 (Force Majeure).
- (e) Bankruptcy; Insolvency. If either Party (or, if applicable, any controlling Affiliate of such Party) undergoes an Insolvency Event, then the other Party may terminate this Agreement in its entirety effective immediately upon written notice to such Party.
- 19.3<u>Effect of Termination</u>. In the event of any termination (except expiration) of this Agreement, unless otherwise expressly provided herein: (i) any liabilities previously accrued will survive; (ii) each Party shall destroy all Confidential Information of the other Party, *provided* that (a) each Party shall be permitted to retain copies of such Confidential Information for the sole purpose of performing any continuing obligations or exercising surviving rights hereunder, (b) any Confidential Information that the Receiving Party is required to retain by any Applicable Laws,

58

including laws and regulations providing for a duty to preserve documents for a civil lawsuit may be retained in accordance with such Applicable Laws, (c) digital backup files automatically generated by the Receiving Party's customary electronic data processing system may be retained and properly stored as confidential files for the sole purpose of backup and will be deleted in accordance with the Receiving Party's retention policy, and (d) a single copy of the Confidential Information may be retained in the files of the Receiving Party for the sole purpose of determining the scope of obligations incurred by it under this Agreement; in each case of the foregoing, the Receiving Party shall abide by the provisions in Article 14 (Confidentiality and Publications); (iii) Chugai shall promptly wind-down its Development, regulatory, and commercial activities, and if applicable Manufacturing, with respect to Product in a manner compliant with Applicable Law, the duties of a responsible sponsor and industry practice, and Chugai shall continue to abide by the terms of this Agreement with respect thereto until such wind-down is complete, including payment of royalties on any Net Sales of Product; (iv) subject to Section 19.4 (Survival of License to Joint IP), all licenses granted hereunder and, subject to Section 19.5 (Survival of Sublicenses), all sublicenses thereunder shall terminate (except to the extent, and only for so long as, required to complete the wind-down contemplated in clause (iii) above); and (v) Chugai shall pay any reimbursement which Rani is entitled to as of the effective date of termination.

19.4<u>Survival of License to Joint IP</u>. Notwithstanding anything to the contrary in this Agreement, in the event of expiration or Chugai's termination of this Agreement other than without cause, the license granted to Chugai under Section 9.1 (License to Chugai) shall convert to, and Rani hereby grants to Chugai an exclusive (even as to Rani, its Affiliates and successors and assigns), sublicensable through multiple tiers, worldwide, fully paid up, perpetual, irrevocable right and license under Rani's interest in the Joint Program Inventions and the Joint Patent Rights to research, Develop, register, Manufacture, have Manufactured, use, sell, offer for sale, have sold, import, export, commercialize, and market the Product in the Field in the Territory.

19.5 Survival of Sublicenses. In the event of any termination (except expiration) of this Agreement, any sublicenses granted by Chugai or its Affiliates under the Rani Licensed IP in accordance with the terms of this Agreement prior to the effective date of termination of this Agreement shall, upon reasonable written request by the relevant Sublicensee within [*] from the effective date of termination, survive any such termination and such sublicense shall become a direct license from Rani to such Sublicensee, provided that such Sublicensee is in material compliance with the applicable provisions of this Agreement and the terms and conditions of the applicable sublicense, and further provided that in no event will Rani be obligated to fulfill any of Chugai's obligations under such sublicense.

59

19.6 Rights to Intellectual Property.

(a) The Parties intend to take advantage of the protections of Section 365(n) (or any successor provision) of the Bankruptcy Code or any analogous provisions in any other country or jurisdiction to the maximum extent permitted by Applicable Law. All rights and licenses now or hereafter granted by Rani to Chugai under or pursuant to any Section of this Agreement are rights to "intellectual property" (as defined in the Bankruptcy Code). If: (a) (i) a case under the Bankruptcy Code is commenced by or against Rani, (ii) this Agreement is rejected as provided in the Bankruptcy Code and (iii) Chugai elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code; then (b) Rani (in any capacity, including debtor-inpossession) and its successors and assigns (including any trustee) will provide to Chugai a copy of all intellectual property licensed hereunder (to the extent not already previously provided), and agrees to grant and hereby grants to Chugai and its Affiliates a right to access and benefit from, and to obtain a pro rata portion of, any "embodiments" of intellectual property pursuant to Section 365(n) of the Bankruptcy Code (which will be deemed to include the Licensed Rani Know-How), and all other embodiments of the intellectual property licensed hereunder. Each Party acknowledges and agrees that "embodiments" of intellectual property within the meaning of Section 365(n) include: (c) copies of research and Development Information; (d) laboratory samples; (e) product samples and inventory; (f) formulas; (g) laboratory notes and notebooks; (h) Information related to preclinical and clinical studies; (i) Regulatory Filings (including Regulatory Approvals); (j) rights of reference in respect of Regulatory Filings (including Regulatory Approvals); (k) tangible Information (including the Licensed Rani Know-How, Licensed Chugai Know-How and Information jointly owned by the Parties with respect to Joint Program Inventions and Joint Patent Rights, as applicable); and (I) Device Manufacturing Data, and Device-Related Product Manufacturing Data. Rani will not interfere with the exercise by Chugai or its Affiliates of rights and licenses to intellectual property licensed hereunder and embodiments thereof in accordance with this Agreement and agrees to [*] assist Chugai and its Affiliates to obtain such intellectual property and embodiments thereof in the possession or control of Third Parties as [*] or desirable for Chugai or its Affiliates or Sublicensees to exercise such rights and licenses in accordance with this Agreement. In addition, in the event clause (a) of this Section 19.6 (Rights to Intellectual Property) applies, to the extent permitted by Applicable Law and reasonably requested by Chugai, Rani shall [*] assign to Chugai (and in such event Chugai shall assume) operational contracts that specifically relate to Product in the Territory and are reasonably required to continue the Development, Manufacture or commercialization of the Product in the Field in the Territory (including [*] to obtain consent for assignment, if required), to the extent permitted under the applicable contract(s). Further, unless and until this Agreement is rejected in any case under the Bankruptcy Code, Rani shall timely

60

perform all of its obligations hereunder or promptly provide all intellectual property (including any embodiment thereof) to Chugai. Notwithstanding anything in this Agreement to the contrary, no rejection of this Agreement by Rani, or any breach of this Agreement by Rani for any reason whatsoever, shall adversely affect or otherwise diminish in any way Chugai's rights under this Agreement. All rights, powers and remedies of Chugai provided in this Section 19.6 (Rights to Intellectual Property) are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code involving Rani.

- (b) The Parties intend and agree that any sale of Rani's assets under Section 363 of the Bankruptcy Code shall be subject to Chugai's rights under Section 365(n), that Chugai cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser "free and clear" of Chugai's rights under this Agreement and Section 365(n) without the express, contemporaneous written consent of Chugai.
- (c) All rights, powers and remedies of Chugai provided in this Section 19.6 (Rights to Intellectual Property) are not in substitution for any other rights, powers and remedies now or hereafter existing at law or in equity (including the Bankruptcy Code). The Parties intend the following rights to extend to the maximum extent permitted by Applicable Law, and to be enforceable under Bankruptcy Code Section 365(n): (a) the right of access to any intellectual property rights (including all embodiments thereof) of Rani or any Third Party with whom Rani contracts to perform an obligation of Rani under this Agreement, and, in the case of any such Third Party, that is [*] for the exploitation of the Device or Oral Delivery Technology or the exercise of any other rights granted to Chugai under this Agreement; (b) the right to contract directly with any Third Party to complete the contracted work; and (c) the right to cure any default under any such agreement with a Third Party and set off the costs thereof against amounts payable to Rani under this Agreement.
- 19.7<u>Insolvency</u>. In the event Rani suffers an Insolvency Event, the Parties agree to work together to complete the Manufacturing Technology Transfer to a mutually-agreed CMO as soon as reasonably practicable and Rani shall establish an escrow of intellectual property relevant to the Product, [*].
- 19.8<u>Additional Surviving Provisions</u>. In addition and without prejudice to the provisions of Section 19.3 (Effect of Termination) and the provisions that are expressly stated to survive termination, in the event of any termination or expiration of this Agreement the following provisions of this Agreement shall survive: Sections 8.10 (Development and Other Costs) (with respect to costs reasonably incurred prior to such termination or expiration), 8.12 (Audits), 10.2 (Program Inventions), 10.3 (Data),

61

10.5(d) (Cooperation), 10.6 (Defense) (with respect to the activities and time period during the Term of this Agreement), 10.8 (Allocation of Recoveries) (with respect to periods prior to termination), 15.4 (Disclaimer of Warranties), and Articles 14 (Confidentiality and Publications) (except with respect to Section 14.4 (Publications and Presentations)); 16 (Limitations of Liability; Insurance); 17 (Indemnification); 19 (Term and Termination) and 20 (Miscellaneous).

19.9Additional Rights and Remedies. Termination or expiration of this Agreement are neither Party's exclusive remedy and will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation. Except as set forth in this Article 19 (Term and Termination) and except for any provisions which by their terms survive expiration or termination of this Agreement, all other rights and obligations will terminate upon termination or expiration of this Agreement.

20. MISCELLANEOUS

20.1<u>Affiliates</u>. Each Party shall have the right to perform its obligations hereunder through its Affiliates, *provided* that such Party shall be responsible for its Affiliates' performance hereunder.

20.2<u>Assignment</u>. Neither Party may assign or otherwise transfer this Agreement without the prior written consent of the other Party; *provided*, *however*, that 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.

20.3Change of Control.

(a) 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. In such event, the Party experiencing the Change of Control shall Segregate the Product and related Information (including Program Data and Confidential Information of the other Party) from the Pre-Transaction Entities to protect the confidentiality of the Information and other Confidential Information of the other Party.

62

- (b) In the event of any Change of Control of Rani, Chugai shall have the right, in its sole and absolute discretion, by written notice delivered to Rani (or its successor) at any time during the [*] following the written notice contemplated by Section 20.3(a) (Change of Control), to (i) terminate any or all provisions of this Agreement providing for any delivery by Chugai to Rani of Compound or Information relating to activities contemplated by this Agreement, save only for the provisions of Article 8 (Payment) and (ii) require Rani and its Affiliates to Segregate the activities conducted by Rani and its Affiliates (and their successors) under this Agreement from the activities conducted by the Pre-Transaction Entities. For the avoidance of doubt, the rights of Chugai under this Section 20.3(b) shall prevail over Section 20.2 in the event of any conflict.
- (c) Rani covenants that, following a Change of Control of Rani, there shall be no material change in the level or nature of efforts or resources expended by Rani and its Affiliates with respect to, or the qualifications and experience of the personnel assigned to (including with respect to the allocation of their time to), its activities under the Development Plan.
- 20.4 Governing Law; Jurisdiction. This Agreement shall be governed by, and enforced and construed in accordance with, the laws of the State of New York without regard to its 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. Any dispute or claim arising under or relating to this Agreement shall be resolved by arbitration initiated by either Party under the Rules of the International Chamber of Commerce ("ICC") then in force. The arbitration will be conducted by a panel of [*] arbitrators, none of whom will be a current or former employee or director, or a then-current stockholder, of either Party, their respective then-current Affiliates, or any Sublicensee/sublicensee. Each Party will be entitled to appoint [*] so appointed will nominate the third arbitrator, within [*] of their appointment. If any Party or the coarbitrators fail to make the appointment as provided herein, the ICC Court of Arbitration will make the appointment in accordance with the ICC Rules. The place of arbitration will be New York, New York, U.S., and the arbitration and all communications and documents relating thereto will be conducted in English. Document production in the arbitration will generally be conducted in accordance with the latest IBA Rules on the Taking of Evidence in International Arbitration. Except to the extent necessary to confirm or enforce an award or to accomplish the purpose of this Agreement, including to exercise its rights and to perform its obligations under this Agreement or as may be required by Applicable Law, the existence, content, or results of an arbitration will be Confidential Information of each of the Parties, and neither a Party nor an arbitrator may disclose such Confidential Information without the prior written consent of the other Party, provided, however, each Party may disclose the content of the award to its Affiliates, Sublicensees and the licensees, employees, agents, consultants, contractors and other representatives who have a legitimate need to know the content of the award

63

or as otherwise permitted under Article 14 (Confidentiality and Publications). The Parties agree that a final judgment in any such arbitration shall be conclusive and may be enforced in other jurisdictions by suits on the judgment or in any other manner provided by law. The United Nations Convention for the International Sale of Goods shall not apply to the transactions contemplated herein.

20.5<u>Construction</u>. 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.

20.6 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.

20.7Entire 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.

20.8Force 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, 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 regular status updates to the other Party for the duration of the effect); and further provided that the affected Party shall [*] 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. If a Force Majeure occurs and is continuing such that a Party cannot perform a material obligation under the Agreement for a period of [*], then the other Party has the right to terminate the Agreement on [*] prior written notice (unless performance has resumed prior to such termination).

64

20.9Equitable Relief. The Parties acknowledge that a breach of this Agreement, including without limitation any unauthorized use of the licensed intellectual property hereunder or disclosure of Confidential Information, may cause irreparable harm for which monetary damages would be an inadequate remedy. Accordingly, the non-breaching Party shall be entitled to seek equitable relief, including injunctive relief and specific performance, in the event of such breach, in addition to all other remedies available at law or in equity. Nothing in this Section 20.9 (Equitable Relief) is intended or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement, and, notwithstanding any provision to the contrary, neither Party may seek equitable relief in the form of termination or recission of this Agreement.

20.10<u>Further Assurances</u>. 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.

20.11No Set-Off. Except as otherwise provided in this Agreement, 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); provided that in the event of Rani undergoes an Insolvency Event, Chugai may exercise a right of set-off of any and all amounts payable by Chugai to Rani under this Agreement against any damages or costs incurred by Chugai as a result of Rani's non-performance or breach of its obligations under this Agreement.

20.12 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 Rani: Rani Therapeutics, LLC

2051 Ringwood Ave San Jose, CA 95131 Attention: Secretary

If to Chugai: Chugai Pharmaceutical Co., Ltd.

1-1 Nihonbashi-Muromachi 2-chome

Chuo-ku, Tokyo 103-8324

Attention: [*]

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 20.12 (Notices).

65

- 20.13<u>Relationship of the Parties</u>. Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute Chugai and Rani as partners, agents or joint venturers, including for Tax purposes. 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.
- 20.14<u>Severability</u>. 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.
- 20.15<u>Third Party Beneficiaries</u>. Except as expressly provided with respect to Rani Indemnitees or Chugai Indemnitees in Article 17 (Indemnification), there are no Third Party beneficiaries intended hereunder and no Third Party shall have any right or obligation hereunder.
- 20.16 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)

66

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

CHUGAI PHARMACEUTICAL CO., LTD.	RANI THERAPEUTICS, LLC
By:	By: [*]
	r j

EXHIBIT 1.6

[*]

EXHIBIT 15.2(A)

[*]

FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT AND SUPPLEMENT

THIS FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT AND SUPPLEMENT (this "Amendment") is dated as of September 30, 2025 (the "First Amendment Date"), and is entered into by and among Rani Therapeutics, LLC, a California limited liability company ("Botrower"), Rani Therapeutics Holdings, Inc., a Delaware corporation ("Parent"), Rani Management Services, Inc., a Delaware corporation, (together with Parent, each individually, a "Guarantor," and collectively, "Guarantor"), Avenue Venture Opportunities Fund, L.P., a Delaware limited partnership (in the capacity as administrative agent and collecteral agent, "Agent," and, together with other lenders from time to time party hereto, each individually, a "Lender," and collectively, "Lenders"). Capitalized terms used herein without definition shall have the same meanings given them in the Loan Agreement (defined herein).

RECITALS

- **A.** Borrower, Guarantor, Lenders and Agent have entered into that certain Loan and Security Agreement (the "LSA") dated as of August 8, 2022, as supplemented by that certain Supplement to the Loan and Security Agreement (the "Supplement") dated as of August 8, 2022, together with related documents and agreements (together, as further amended, restated, or otherwise modified from time to time, hereinafter collectively referred to as the "Loan Agreement").
- **B.** Borrower, Guarantor, Lenders and Agent now desire to amend the Loan Agreement upon the terms and conditions more fully set forth in this Amendment.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing Recitals, the parties hereto agree as follows:

- 1. Amendments.
- 1.1 The following definitions in Part I of the Supplement are hereby amended and restated in their entirety, as set forth below:
 - **"Interest-only Period"** means the period commencing on the Closing Date and continuing until August 31, 2024; provided, however, such period shall recommence on October 1, 2025 and continue until October 31, 2025.
- **1.2** A new Section 10 is hereby inserted immediately after Section 9 of Part 2 of the Supplement, as set forth below:
 - 10. Conversion Right. The Lenders shall have the right, in their discretion, but not the obligation, while the Loan is outstanding, to convert an amount of up to Six Million Dollars (\$6,000,000.00) of the principal amount of the outstanding Growth Capital Loans (the "Conversion Option") into equity on the same terms as the first bona fide equity financing that closes after the First Amendment Date (the "Next Equity Financing"), inclusive of all the incentive equity terms granted to the Next Equity Financing, including without limitation warrant coverage. Notwithstanding the foregoing, such Conversion shall be subject to the rules of the Nasdaq Stock Market in all respects and shall expire after the completion of the Next Equity Financing. The Conversion Option will be exercised by such

Lenders delivering a written, signed conversion notice to the Borrower in accordance with this Section 10, which will include (i) the date of which the conversion notice is given, (ii) a statement to the effect that the applicable Lender is exercising the Conversion Option, (iii) the amount in respect of which the Conversion Option is being exercised and the number of shares and warrants (or other derivative securities to be issued) issued, (iv) a date on which the issuance of the shares is to take place, and (v) the Lender becoming a party to the definitive agreements effecting the Next Equity Financing.

2. WARRANTS. As additional consideration for the making of this Amendment, Parent shall amend that certain Warrant delivered to Lender on August 8, 2022 with an Amendment to Warrant substantially in the form of Exhibit A attached hereto (the "Warrant Amendment")

3. Borrower's Representations And Warranties. Borrower represents and warrants that:

- a. Immediately upon giving effect to this Amendment (i) the representations and warranties contained in the Loan Agreement are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct in all material respects as of such date), and (ii) no Event of Default has occurred and is continuing.
- b. Borrower and Guarantors have the organizational power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment.
- c. The articles of organization, certificates of incorporation, bylaws and other organizational documents of Borrower and Guarantors delivered to Lenders on the Closing Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect.
- d. The execution and delivery by Borrower and Guarantors of this Amendment and the performance by Borrower and Guarantors of their obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized by all necessary company action on the part of Borrower and Guarantors.
- e. This Amendment has been duly executed and delivered by Borrower and Guarantors and is the binding obligation of Borrower and Guarantors, enforceable against them in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights; and
- f. As of the date hereof, to their best knowledge, they have no defenses against the obligations to pay any amounts arising under the Loan and Security Agreement. Borrower and Guarantors acknowledge that, to their best knowledge, Lenders and Agent have acted in good faith and have conducted in a commercially reasonable manner its relationships with Borrower and Guarantors in connection with this Amendment and in connection with the Loan Documents.

Borrower and Guarantors understand and acknowledge that Lenders and Agent are entering into this Amendment in reliance upon, and in partial consideration for, the above representations and warranties, and agrees that such reliance is reasonable and appropriate.

- **4. LIMITATION.** The amendments set forth in this Amendment shall be limited precisely as written and shall not be deemed (a) to be a waiver or modification of any other term or condition of the Loan Agreement or of any other instrument or agreement referred to therein or to prejudice any right or remedy which Lenders or Agent may now have or may have in the future under or in connection with the Loan Agreement (as amended hereby) or any instrument or agreement referred to therein; or (b) to be a consent to any future amendment or modification or waiver to any instrument or agreement the execution and delivery of which is consented to hereby, or to any waiver of any of the provisions thereof. Except as expressly amended hereby, the Loan Agreement shall continue in full force and effect.
- **5. EFFECTIVENESS.** This Amendment shall become effective upon Lenders' and Agent's receipt of the following:
 - **5.1** this Amendment, duly executed by Borrower;
 - **5.2** the Warrant Amendment, duly executed by Parent;
- **5.3** reimbursement of Lenders' and Agent's fees and expenses, including all reasonable documented attorneys' fees, expenses and disbursements, incurred through the date of this Amendment.
- **6.** COUNTERPARTS. This Amendment may be signed in any number of counterparts, and by different parties hereto in separate counterparts, with the same effect as if the signatures to each such counterpart were upon a single instrument. All counterparts shall be deemed an original of this Amendment. This Amendment may be executed by facsimile, portable document format (.pdf) or similar technology signature, and such signature shall constitute an original for all purposes.
- **7.** Incorporation By Reference. The provisions of Sections 9.11 and 9.12 of the Loan Agreement shall be deemed incorporated herein by reference, *mutatis mutandis*.
- **8.** ELECTRONIC SIGNATURES. This Amendment may be executed by electronic signatures. Borrower, Lenders and Agent expressly agree to conduct the transactions contemplated by this Amendment and the other Loan Documents by electronic means (including, without limitation, with respect to the execution, delivery, storage and transfer of this Amendment and each of the other Loan Documents by electronic means and to the enforceability of electronic Loan Documents). Delivery of an executed signature page to this Amendment and each of the other Loan Documents by facsimile or other electronic mail transmission (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) shall be effective as delivery of a manually executed counterpart hereof and thereof, as applicable. The words "execution," "signed," "signature" and words of like import herein shall be deemed to include electronic signatures or the keeping of records in electronic form, each of which shall be of the same legal effect, validity and enforceability as a manually executed signature or the use of a paper-based recordkeeping systems, as the case may be, to the extent and as provided for in any applicable law, including, without limitation, any state law based on the Uniform Electronic Transactions Act.

[Signature Pages Follow on Next Page.]

as of the date first written above. BORROWER: RANI THERAPEUTICS, LLC Name: Svai Sanford Title: Chief Financial Officer GUARANTOR: RANI THERAPEUTICS HOLDINGS, INC. RANI MANAGEMENT SERVICES, INC. By: By: Svai Sanford Svai Sanford Name: Name: Chief Financial Officer Chief Financial Officer Title: Title: LENDER: AVENUE VENTURE OPPORTUNITIES FUND, L.P. By: Avenue Venture Opportunities Partners, LĹĊ Its: General Partner Ву: _ Sonia Gardner Name: Title: Member AGENT: AVENUE VENTURE OPPORTUNITIES FUND, L.P. By: Avenue Venture Opportunities Partners, LLC Its: General Partner

In Witness Whereof, the parties have duly authorized and caused this Amendment to be executed

Signature Pages (First Amendment to Loan and Security Agreement and Supplement)

By: __ Name:

Title:

Sonia Gardner

Member

Exhibit A

(Amendment No. 1 to Warrant Issued to Avenue Venture Opportunities Fund, L.P.)

CERTIFICATION

I, Talat Imran, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Rani Therapeutics Holdings, Inc.;
- 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;
- 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: November 6, 2025

/s/ Talat Imran

Talat Imran Chief Executive Officer (Principal Executive Officer)

CERTIFICATION

I, Svai Sanford, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Rani Therapeutics Holdings, Inc.;
- 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;
- 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: November 6, 2025

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

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:

- The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2025, 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: November 6, 2025

In Witness Whereof, the undersigned have set their hands hereto as of the 6th day of November, 2025

/s/ Talat Imran
Talat Imran
Svai Sanford
Chief Executive 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.