UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-40672

RANI THERAPEUTICS HOLDINGS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**86-3114789**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2051 Ringwood Avenue **San Jose, California**	**95131**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

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

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

As of November 8, 2022, the registrant had 24,719,972 shares of Class A common stock, $0.0001 par value per share, outstanding, 24,640,196 shares of Class B common stock, $0.0001 par value per share, outstanding and no shares of Class C common stock, $0.0001 par value per share, outstanding. Certain holders of units of the registrant's consolidated subsidiary, Rani Therapeutics, LLC, who do not hold shares of the registrant's Class B common stock can exchange their units of Rani Therapeutics, LLC for 1,387,471 shares of the registrant's Class A common stock.

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Unless otherwise stated or the context otherwise requires, the terms "we," "us," and "our," and similar references refer to Rani Therapeutics Holdings, Inc. ("Rani Holdings") and its consolidated subsidiaries, Rani Therapeutics, LLC ("Rani LLC") and Rani Management Systems, Inc. ("RMS").

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, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

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

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

- the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the impact of the COVID-19 pandemic and the conflict between Ukraine and Russia on our business;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- our realization of any benefit from our organizational structure, taking into account our obligations under the Tax Receivable Agreement (defined herein) and the impact of any payments required to be made thereunder on our liquidity and financial condition; and
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act").

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions described in the section titled "Risk Factors" and elsewhere in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2022. 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)

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 27,219	$ 117,453
Marketable securities	70,952	—
Prepaid expenses and other current assets	2,549	2,142
Total current assets	100,720	119,595
Restricted cash equivalents	500	—
Property and equipment, net	5,680	4,612
Operating lease right-of-use asset	1,302	—
Total assets	$ 108,202	$ 124,207
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,790	$ 1,080
Related party payable	55	126
Accrued expenses	4,357	1,434
Operating lease liability, current portion	984	—
Total current liabilities	7,186	2,640
Operating lease liability, less current portion	318	—
Long-term debt	14,091	—
Total liabilities	21,595	2,640
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, 2022 and December 31, 2021	—	—
Class A common stock, $0.0001 par value - 800,000 shares authorized; 24,720 and 19,712 issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	2	2
Class B common stock, $0.0001 par value - 40,000 shares authorized; 24,639 and 29,290 issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	3	3
Class C common stock, $0.0001 par value - 20,000 shares authorized; none issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	72,379	55,737
Accumulated other comprehensive loss	(57)	—
Accumulated deficit	(30,133)	(8,331)
Total stockholders' equity attributable to Rani Therapeutics Holdings, Inc.	42,194	47,411
Non-controlling interest	44,413	74,156
Total stockholders' equity	86,607	121,567
Total liabilities and stockholders' equity	$ 108,202	$ 124,207

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)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Contract revenue	$ —	$ —	$ —	$ 2,717
Operating expenses				
Research and development	9,103	11,959	26,221	19,065
General and administrative	7,239	15,822	19,748	21,889
Total operating expenses	$ 16,342	$ 27,781	$ 45,969	$ 40,954
Loss from operations	(16,342)	(27,781)	(45,969)	(38,237)
Other income (expense), net				
Interest income and other, net	379	13	430	73
Loss on extinguishment of debt	—	(700)	—	(700)
Interest expense and other, net	(352)	(110)	(352)	(467)
Change in estimated fair value of preferred unit warrant	—	(85)	—	(371)
Loss before income taxes	(16,315)	(28,663)	(45,891)	(39,702)
Income tax expense	107	(37)	(111)	(81)
Net loss	$ (16,208)	$ (28,700)	$ (46,002)	$ (39,783)
Net loss attributable to non-controlling interest	(8,253)	(25,558)	(24,200)	(36,641)
Net loss attributable to Rani Therapeutics Holdings, Inc.	$ (7,955)	$ (3,142)	$ (21,802)	$ (3,142)
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc., basic and diluted	$ (0.33)	$ (0.16)	$ (0.93)	$ (0.16)
Weighted-average Class A common shares outstanding—basic and diluted	24,468	19,437	23,449	19,437

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

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss	$ (16,208)	$ (28,700)	$ (46,002)	$ (39,783)
Other comprehensive loss				
Net unrealized loss on marketable securities	(118)	—	(118)	—
Comprehensive loss	$ (16,326)	$ (28,700)	$ (46,120)	$ (39,783)
Comprehensive loss attributable to non-controlling interest	(8,314)	(25,558)	(24,261)	(36,641)
Comprehensive loss attributable to Rani Therapeutics Holdings, Inc.	$ (8,012)	$ (3,142)	$ (21,859)	$ (3,142)

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

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

	Class A Common Stock		Class B Common Stock						
	Shares	Amount	Shares	Amount	Additional Paid In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Non-Controlling Interest	Total Stockholders' Equity
Balance at December 31, 2021	19,712	$ 2	29,290	$ 3	$ 55,737	$ —	$ (8,331)	$ 74,156	$ 121,567
Effect of exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC	4,675	—	(4,517)	—	—	—	—	—	—
Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC	—	—	—	—	10,928	—	—	(10,928)	—
Equity-based compensation	—	—	—	—	1,268	—	—	1,637	2,905
Net loss	—	—	—	—	—	—	(6,223)	(7,605)	(13,828)
Balance at March 31, 2022	24,387	$ 2	24,773	$ 3	$ 67,933	$ —	$ (14,554)	$ 57,260	$ 110,644
Forfeiture of restricted stock awards	(3)	—	—	—	(3)	—	—	(3)	(6)
Effect of exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC	110	—	(110)	—	—	—	—	—	—
Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC	—	—	—	—	126	—	—	(126)	—
Equity-based compensation	—	—	—	—	1,930	—	—	2,052	3,982
Net loss	—	—	—	—	—	—	(7,624)	(8,342)	(15,966)
Balance at June 30, 2022	24,494	$ 2	24,663	$ 3	$ 69,986	$ —	$ (22,178)	$ 50,841	$ 98,654
Forfeiture of restricted stock awards	(2)	—	—	—	(3)	—	—	(4)	(7)
Effect of exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC	24	—	(24)	—	—	—	—	—	—
Issuance of warrants	—	—	—		503	—	—	—	503
Issuance of common stock under employee equity plans, net of shares withheld for tax settlement	204	—	—	—	(626)	—	—	—	(626)
Non-controlling interest adjustment for changes in proportionate ownership in Rani LLC	—	—	—	—	372	—	—	(372)	—
Equity-based compensation	—	—	—	—	2,147	—	—	2,262	4,409
Net loss	—	—	—	—	—	—	(7,955)	(8,253)	(16,208)
Other comprehensive loss	—	—	—	—	—	(57)	—	(61)	(118)
Balance at September 30, 2022	24,720	$ 2	24,639	$ 3	$ 72,379	$ (57)	$ (30,133)	$ 44,413	$ 86,607

	Convertible Preferred Units	Members' Deficit	Class A Common Stock		Class B Common Stock		Additional Paid In Capital	Accumulated Deficit	Non-Controlling Interest	Total Stockholders' Equity/Members' (Deficit)
			Shares	Amount	Shares	Amount				
Activity prior to initial public offering ("IPO") and related Organizational Transactions										
Balance at December 31, 2020	$ 184,714	$ (113,339)	—	$ —	—	$ —	$ —	$ —	$ —	$ (113,339)
Issuance of Series E preferred units	6,320	—	—	—	—	—	—	—	—	—
Exercise of warrant for common units	—	13	—	—	—	—	—	—	—	13
Equity-based compensation from secondary sales transactions	—	453	—	—	—	—	—	—	—	453
Net loss	—	(5,598)	—	—	—	—	—	—	—	(5,598)
Balance at March 31, 2021	$ 191,034	$ (118,471)	—	$ —	—	$ —	$ —	$ —	$ —	$ (118,471)
Equity-based compensation	—	282	—	—	—	—	—	—	—	282
Net loss	—	(5,485)	—	—	—	—	—	—	—	(5,485)
Balance at June 30, 2021	$ 191,034	$ (123,674)	—	$ —	—	$ —	$ —	$ —	$ —	$ (123,674)
Equity-based compensation	—	17,042	—	—	—	—	—	—	—	17,042
Exercise of warrant for common units	—	13	—	—	—	—	—	—	—	13
Settlement of preferred unit warrant liability	691	—	—	—	—	—	—	—	—	—
Net loss	—	(20,644)	—	—	—	—	—	—	—	(20,644)
Effects of the IPO and related Organizational Transactions										
Effects of Organizational Transactions	(191,725)	127,263	12,048	1	29,290	3	18,106	—	46,352	191,725
Issuance of Class A common stock in connection with the IPO, net of issuance costs of $10,686	—	—	7,667	1	—	—	73,647	—	—	73,648
Non-controlling interest adjustment for purchase of newly issued Class A units of Rani LLC with proceeds from the IPO	—	—	—	—	—	—	(37,895)	—	37,895	—
Net loss	—	—	—	—	—	—	—	(149)	(233)	(382)
Activity subsequent to the IPO and related Organizational Transactions										
Equity-based compensation	—	—	—	—	—	—	646	—	1,010	1,656
Forfeiture of restricted stock awards	—	—	(3)	—	—	—	(1)	—	(1)	(2)
Net loss	—	—	—	—	—	—	—	(2,993)	(4,681)	(7,674)
Balance at September 30, 2021	$ —	$ —	19,712	$ 2	29,290	$ 3	$ 54,503	$ (3,142)	$ 80,342	$ 131,708

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

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

	For the Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (46,002)	$ (39,783)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation expense	11,283	19,431
Non-cash operating lease expense	528	—
Depreciation and amortization	374	384
Net accretion and amortization of investments in marketable securities	(210)	—
Amortization of debt discount and issuance costs	19	—
Change in fair value of preferred unit warrant liability	—	371
Loss on extinguishment of debt	—	700
Other	—	108
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(117)	(2,455)
Accounts payable	377	674
Accrued expenses	2,461	2,346
Operating lease liabilities	(528)	—
Related party payable	(71)	145
Deferred revenue	—	(2,717)
Net cash used in operating activities	(31,886)	(20,796)
Cash flows from investing activities		
Purchases of marketable securities	(70,890)	—
Purchases of property and equipment	(1,089)	(235)
Net cash used in investing activities	(71,979)	(235)
Cash flows from financing activities		
Proceeds from the issuance of long-term debt and warrants, net of issuance costs	14,671	—
Tax withholdings paid on behalf of employees for net share settlement	(626)	—
Proceeds from employee stock purchase plan	194	—
Payment of deferred financing costs	(108)	—
Proceeds from issuance of Class A common stock sold in the IPO, net of issuance costs	—	74,218
Proceeds from issuance of preferred units, net of issuance costs	—	6,320
Principal and interest repayments from related party for note receivable	—	1,720
Proceeds from exercise of warrants for common units	—	26
Repayment of the Paycheck Protection Program Loan	—	(1,254)
Repayment of convertible note	—	(3,314)
Net cash provided by financing activities	14,131	77,716
Net (decrease) increase in cash, cash equivalents and restricted cash equivalents	(89,734)	56,685
Cash and cash equivalents, beginning of period	117,453	73,058
Cash, cash equivalents and restricted cash equivalents, end of period	$ 27,719	$ 129,743
Supplemental disclosures of non-cash investing and financing activities		
Property and equipment purchases included in accounts payable and accrued expenses	$ 352	$ 284
Exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC	$ 74,790	$ —
Issuance costs deducted from long-term debt proceeds	$ 928	$ —
Right-of-use assets obtained in exchange for new operating lease liabilities	$ 514	$ —
Deferred financing costs included in prepaid expenses	$ 260	$ —
Deferred financing costs included in accrued expenses	$ 152	$ 570
Issuance costs included in accrued expenses	$ 97	$ —
Interest income receivable included in prepaid expenses	$ 30	$ —
Exchange of Class A Units of Rani LLC from the Former LLC Owners	$ —	$ 132,527
Settlement of preferred unit warrant liability	$ —	$ 691

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

1. Organization and Nature of Business

Description of Business

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

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

Initial Public Offering and Organizational Transactions

In August 2021, the Company closed its IPO and sold 7,666,667 shares of its Class A common stock, including shares issued pursuant to the exercise in full of the underwriters' option, for cash consideration of $11.00 per share and received approximately $73.6 million in net proceeds, after deducting underwriting discounts, offering costs and commissions. The Company used the proceeds from the IPO to purchase 7,666,667 newly issued economic nonvoting Class A units ("Class A Units") of Rani LLC.

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

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

The Continuing LLC Owners are entitled to exchange, subject to the terms of the Rani LLC Agreement, the Class A Units they hold in Rani LLC, together with the shares they hold of the Company Class B common stock (together referred to as a "Paired Interest"), in return for shares of the Company's Class A common stock on a one-for-one basis provided that, at the Company's election, the Company has the ability to effect a direct exchange of such Class A common stock or make a cash payment equal to a volume weighted average market price of one share of Class A common stock for each Paired Interest redeemed. Any shares of Class B common stock will be cancelled on a one-for-one basis if, at the election of the Continuing LLC Owners, the Company redeems or exchanges such Paired Interest pursuant to the terms of the Rani LLC Agreement. As of September 30, 2022, certain individuals who continue to own interests in Rani LLC but do not hold shares of the Company's Class B common stock ("non-corresponding Class A Units") have the ability to exchange their non-corresponding Class A Units of Rani LLC for 1,387,471 shares of the Company's Class A common stock.

Liquidity

The Company has incurred recurring losses since its inception, including net losses of $46.0 million for the nine months ended September 30, 2022. As of September 30, 2022, the Company had an accumulated deficit of $30.1 million and for the nine months ended September 30, 2022 had negative cash flows from operations of $31.9 million. The Company expects to continue to generate operating losses and negative operating cash flows for the foreseeable future as it continues to develop the RaniPill capsule. The Company expects that its cash, cash equivalents, restricted cash equivalents and marketable securities of $98.7 million as of September 30, 2022 will be sufficient to fund its operations through at least twelve months from the date the condensed consolidated financial statements are issued. The Company expects to finance its future operations with its existing cash and through strategic financing opportunities that could include, but are not limited to, future offerings of its equity, such as "at the market offerings " as defined in Rule 415(a)(4) under the Securities Act, collaboration or licensing agreements, or the incurrence of debt. However, there is no guarantee that any of these strategic or financing opportunities will be executed or realized on favorable terms, if at all, and some could be dilutive to existing stockholders and holders of interests in the Company. The Company will not generate any revenue from product sales unless, and until, it successfully completes clinical development and obtains regulatory approval for the RaniPill capsule. If the Company obtains regulatory approval for the RaniPill capsule, it expects to incur significant expenses related to developing its internal commercialization capability to support manufacturing, product sales, marketing, and distribution.

The Company's ability to raise additional capital through either the issuance of equity or debt, is dependent on a number of factors including, but not limited to, the market interest of the Company, which itself is subject to a number of development and business risks and uncertainties, as well as the uncertainty that the Company would be able to raise such additional capital at a price or on terms that are favorable to the Company. Market volatility resulting from the novel coronavirus disease ("COVID-19") pandemic or other factors could also adversely impact the Company's ability to access capital when and as needed.

2. Summary of Significant Accounting Policies

Basis of Presentation

These condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

The Company operates and controls all of the business and affairs of Rani LLC, and through Rani LLC and its subsidiary, 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.

The Organizational Transactions were considered transactions between entities under common control. As a result, the condensed consolidated financial statements for periods prior to the IPO and the Organizational Transactions have been adjusted to combine the previously separate entities for presentation purposes.

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 except for the adoption of the new lease accounting standard. Operating results for the three and nine months ended September 30, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022 or for any future period.

The consolidated balance sheet as of December 31, 2021 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 2021 consolidated financial statements and notes included in the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2022.

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. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Estimates include, but are not limited to equity-based compensation expense, accrued research and development costs, the measurement of right-of-use assets and lease liabilities and related incremental borrowing rate, the fair value of warrants and, until the occurrence of the Company's IPO, the fair value of Profits Interests and preferred unit warrants. 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, 2021. Except as noted below, there have been no material changes in the Company's significant accounting policies during the nine months ended September 30, 2022.

Concentrations of Credit Risk and Other Risks and Uncertainties

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

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The extent to which the COVID-19 pandemic will further directly or indirectly impact the Company's results of operation and financial condition has been and will continue to be driven by many factors, most of which are beyond the Company's control and ability to forecast. Because of these uncertainties, the Company cannot estimate how long or to what extent COVID-19 will impact the Company's operations.

Cash Equivalents and Restricted Cash Equivalents

The Company considers all cash held on deposit and highly liquid investments purchased with original or remaining maturities of less than three months at the date of purchase to be cash equivalents. Restricted cash equivalents consist of cash collateral required by a bank in connection with the Company's commercial credit cards program.

The following table provides a reconciliation of cash, cash equivalents and restricted cash equivalents reported within 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, 2022 and 2021:

	As of September 30,	
	2022	2021
End of Period:		
Cash and cash equivalents	$ 27,219	$ 129,743
Restricted cash equivalents	500	—
Total cash, cash equivalents and restricted cash equivalents	$ 27,719	$ 129,743

Marketable Securities

The Company invests its excess cash in marketable securities with high credit ratings including securities issued by U.S. and international governments and their agencies, corporate debt securities and commercial paper. The Company has assessed U.S. government treasuries as Level 1 and all other marketable securities as Level 2 within the fair value hierarchy of Accounting Standard Codification ("ASC") Topic 820. All the Company's marketable securities have been accounted for as available-for-sale and carried at fair value. The Company classifies all its available-for-sale marketable securities, including those with maturity dates beyond one year, as current assets on the condensed consolidated balance sheets as the Company may sell these securities at any time for use in current operations even if they have not yet reached maturity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income and other, net on the condensed consolidated

statements of operations and comprehensive loss. Realized gains and losses on marketable securities are included in other income (expense) on the condensed consolidated statements of operations. Gains and losses on sales are recorded based on the trade date and determined using the specific identification method.

The Company has adopted Accounting Standard Codification Topic 326. Under Subtopic 326-30, the Company periodically assesses its available-for-sale marketable securities for impairment. For debt securities in an unrealized loss position, this assessment first takes into account the Company's intent to sell, or whether it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis. If either of these criteria are met, the debt security's amortized cost basis is written down to fair value through interest expense and other, net. For debt securities in an unrealized loss position that do not meet the aforementioned criteria, the Company assesses whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and any adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss may exist, the present value of cash flows expected to be collected from the security are compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses will be recorded in other income (expense), net, limited by the amount that the fair value is less than the amortized cost basis. Any additional impairment not recorded through an allowance for credit losses is recognized in other comprehensive loss. Changes in the allowance for credit losses are recorded as provision for (or reversal of) credit loss expense. Losses are charged against the allowance when management believes the uncollectability of an available-for-sale marketable security is confirmed or when either of the criteria regarding intent or requirement to sell is met. These changes are recorded in other income (expense), net. The Company has made an accounting policy election to not measure an allowance for credit loss for accrued interest receivables and will recognize a credit loss for accrued interest receivables when the loss becomes probable and estimable. As of September 30, 2022, interest income receivable recorded as a component of prepaid expenses and other current assets on the condensed consolidated balance sheet was de minimis.

Fair Value of Financial Instruments

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

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

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

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

The carrying values of the Company's cash, cash equivalents, restricted cash equivalents, prepaid expenses, accounts payable, and accruals approximate their fair value due to their short-term nature.

Leases

Prior to January 1, 2022, the Company had one cancelable operating lease agreement for its corporate headquarters and recognized related rent expense on a straight-line basis over the term of the lease. The Company's lease agreement contained termination and renewal options. The Company did not assume termination nor renewals options in its determination of the lease term unless they were deemed to be reasonably certain at the renewal of the lease. The Company began recognizing rent expense on the date that it obtained the legal right to use and control the leased space.

Subsequent to the adoption of the new leasing standard on January 1, 2022, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present at the inception of the arrangement and if such a lease is classified as a financing lease or operating lease. The Company has elected not to recognize on the balance sheet leases with terms of one year or less. For any arrangement that is considered to be a lease with a term greater than one year, the Company recognizes a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities in the Company's condensed consolidated balance sheet as of September 30, 2022.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease contract. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the expected lease term. In determining the net present value of lease payments, the interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rate ("IBR"), which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the ROU asset may be required for items such as initial direct costs paid or incentives received and impairment charges if the Company determines the ROU asset is impaired. The Company considers a lease term to be the noncancelable period during which it has the right to use the underlying asset, including any periods where it is reasonably certain the Company will exercise the option to extend the contract. Periods covered by an option to extend are included in the lease term if the lessor controls the exercise of that option.

The operating lease ROU assets also include any lease payments made and exclude lease incentives. Lease expense is recognized on a straight-line basis over the expected lease term. The Company has elected to not separate lease and non-lease components for its leased assets and accounts for all lease and non-lease components of its agreements as a single lease component. The lease components resulting in a ROU asset have been recorded on the condensed consolidated balance sheet and amortized as lease expense on a straight-line basis over the lease term.

Long-Term Debt with Detachable Warrants

Detachable warrants are evaluated for the classification of warrants as either equity instruments, derivative liabilities, or liabilities depending on the specific terms of the warrant agreement. In circumstances in which debt is issued with equity-classified warrants, the proceeds from the issuance of debt are first allocated to the debt and the warrants at their relative estimated fair values. The portion of the proceeds allocated to the warrants are accounted for as paid-in capital and a debt discount. The remaining proceeds, as further reduced by discounts created by the bifurcation of embedded derivatives and beneficial conversion features, are allocated to the debt. The Company accounts for debt as liabilities measured at amortized cost and amortizes the resulting debt discount from the allocation of proceeds, to interest expense using the effective interest method over the expected term of the debt instrument. The Company considers whether there are any embedded features in debt instruments that require bifurcation and separate accounting as derivative financial instruments.

Tax Receivable Agreement

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

A liability for the payable to parties subject to the TRA, and a reduction to stockholders' equity, is accrued when (i) an exchange of a Paired Interest or non-corresponding Class A Units of Rani LLC has occurred and (ii) when it is deemed probable that the Tax Attributes associated with the exchange will be used to reduce the Company's taxable income based on the contractual percentage of the benefit of Tax Attributes that the Company expects to receive over a period of time (Note 14).

Comprehensive Loss

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

Net Loss Per Class A Common Share Attributable to Rani Holdings

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

Non-Controlling Interest

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

In August 2021, based on the Organizational Transactions, Rani Holdings became the sole managing member of Rani LLC. As of September 30, 2022, Rani Holdings held approximately 49% of the Class A Units of Rani LLC, and approximately 51% of the outstanding Class A Units of Rani LLC are held by the Continuing LLC Owners. Therefore, the Company reports NCI based on the Class A Units of Rani LLC held by the Continuing LLC Owners on its condensed consolidated balance sheet as of September 30, 2022. Income or loss attributed to the NCI in Rani LLC is based on the Class A Units outstanding during the period for which the income or loss is generated and is presented on the condensed consolidated statements of operations and comprehensive loss.

Future exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC will result in a change in ownership and reduce or increase the amount recorded as NCI and increase or decrease additional paid-in-capital when Rani LLC has positive or negative net assets, respectively. From the date of the Organizational Transactions to September 30, 2022, there were 4,650,195 exchanges of Paired Interests and 158,051 exchanges of non-corresponding Class A Units of Rani LLC for an equal number of shares of the Company's Class A common stock.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, Leases (“Topic 842”), as subsequently amended, to improve financial reporting and disclosures about leasing transactions. The Company adopted this standard on January 1, 2022 using the modified retrospective approach and elected the package of practical expedients permitted under transition guidance, which allowed the Company to carry forward its historical assessments of: 1) whether contracts are or contain leases, 2) lease classification and 3) initial direct costs, where applicable. The Company did not elect the practical expedient allowing the use-of-hindsight which would require the Company to reassess the lease term of its leases based on all facts and circumstances through the effective date and did not elect the practical expedient pertaining to land easements as this is not applicable to the current contract portfolio. The Company elected the post-transition practical expedient to not separate lease components from non-lease components for all existing lease classes. The Company also elected a policy of not recording leases on its condensed balance sheets when the leases have a term of twelve months or less and the Company is not reasonably certain to elect an option to purchase the leased asset.

The adoption of this standard resulted in the recognition of a ROU asset and lease liabilities of $1.3 million, respectively. The adoption of the standard had no impact on the Company’s condensed consolidated statements of operations and comprehensive loss or to its cash flows from or used in operating, financing, or investing activities on its condensed consolidated statements of cash flows. No cumulative-effect adjustment within accumulated deficit was required to be recorded as a result of adopting this standard.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses* (“ASU 2016-13”), that revises the measurement of credit losses for most financial instruments measured at amortized cost, including trade receivables, from an incurred loss methodology to an expected loss methodology which results in earlier recognition of credit losses. Under the incurred loss model, a loss is not recognized until it is probable that the loss-causing event has already occurred. The standard introduces a forward-looking expected credit loss model that requires an estimate of the expected credit losses over the life of the instrument by considering all relevant information including historical experience, current conditions, and reasonable and supportable forecasts that affect collectability. In addition, the standard also modifies the impairment model for available-for-sale debt securities, which are measured at fair value, by eliminating the consideration for the length of time fair value has been less than amortized cost when assessing credit loss for a debt security and provides for reversals of credit losses through income upon credit improvement. The Company early adopted this standard on July 1, 2022, for the interim period ended September 30, 2022. Based on the composition of the Company's investment portfolio, which reflects the Company's primary investment objective of capital preservation, the adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements or related disclosures.

3. Cash Equivalents, Restricted Cash Equivalents and Marketable Securities

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

	As of September 30, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 23,286	$ —	$ —	$ 23,286
Total cash equivalents	23,286	—	—	23,286
Restricted cash equivalents:				
Money market funds	500	—	—	500
Total cash equivalents and restricted cash equivalents	23,786	—	—	23,786
Marketable securities:				
U.S. Treasuries	37,738	—	(75)	37,663
Commercial paper	26,417	—	—	26,417
Corporate debt securities	5,434	—	(38)	5,396
International government	1,481	—	(5)	1,476
Total marketable securities	71,070	—	(118)	70,952
Total cash equivalents, restricted cash equivalents and marketable securities	$ 94,856	$ —	$ (118)	$ 94,738

	As of December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 115,595	$ —	$ —	$ 115,595
Total cash equivalents	$ 115,595	$ —	$ —	$ 115,595

As of September 30, 2022, all marketable securities held have maturity dates within one year or less. 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, 2022, 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, 2022.

4. Fair Value Measurements

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

	As of September 30, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 23,286	$ —	$ —	$ 23,286
Restricted cash equivalents:				
Money market funds	500	—	—	500
Marketable securities				
U.S. Treasuries	37,663	—	—	37,663
Commercial paper	—	26,417	—	26,417
Corporate debt securities	—	5,396	—	5,396
International government	—	1,476	—	1,476
Total assets	$ 61,449	$ 33,289	$ —	$ 94,738

	As of December 31, 2021			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 115,595	$ —	$ —	$ 115,595
Total assets	$ 115,595	$ —	$ —	$ 115,595

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

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

For the three and nine months ended September 30, 2022, as further discussed in Note 13, the Company issued Level 3 equity classified warrants of $0.5 million in connection with the loan and security agreement that were estimated on the date of issuance using the Black-Scholes valuation model which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield. Such assumptions represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

For the three and nine months ended September 30, 2021, the Company held a Level 3 liability associated with preferred unit warrants that were issued in conjunction with a loan and security agreement. These preferred unit warrants were settled with Class A common stock as part of the IPO and Organizational Transactions.

The following tables set forth a summary of the changes in the fair value of the Company's liability measured using Level 3 inputs (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Balance at beginning of period	$ —	$ 606	$ —	$ 320
Change in estimated fair value of Series E warrants	—	85	—	371
Settlement of Series E warrants	—	(691)	—	(691)
Balance at end of period	$ —	$ —	$ —	$ —

5. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2022	December 31, 2021
Payroll and related	$ 2,950	$ 202
Accrued professional fees	471	213
Accrued preclinical and clinical trial costs	422	621
Other	514	398
Total accrued expenses	$ 4,357	$ 1,434

6. Evaluation Agreement

Takeda

Takeda Pharmaceutical Company, Limited ("Takeda") was collaborating with the Company to conduct research on the use of the RaniPill capsule for the oral delivery of factor VIII ("FVIII") therapy for patients with hemophilia A. The agreement granted Takeda a right of first negotiation to a worldwide, exclusive license under the Company's intellectual property related to a FVIII-RaniPill therapeutic. Takeda paid the Company up-front payments of $5.9 million upon execution of and subsequent

modifications to the agreement. Upon the initial evaluation services being completed, Takeda had an option to pay the Company $3.0 million to perform later stage evaluation services. Takeda also had the ability to terminate the agreement at any time by providing 30 days written notice after the effective date of the agreement. Unless terminated early, the agreement term ended upon the expiration of the right of first negotiation period which is 120 days after the completion of the evaluation services. The Takeda agreement could be terminated for cause by either party based on uncured material breach by the other party or bankruptcy of the other party. Upon early termination, all ongoing activities under the agreement and all mutual collaboration, development and commercialization licenses and sublicenses would terminate.

The Company identified one material promise under the Takeda agreement, the obligation to perform services to evaluate if Takeda's FVIII therapy can be orally delivered using the RaniPill capsule ("Research and Development Services"), which was concluded to be a single performance obligation.

In May 2021, the Company received written notice from Takeda as to their intent to terminate the contract for convenience. Due to the delivery of the termination notice, the Company determined that there were no further enforceable rights and obligations under the agreement beyond May 2021 and the remaining $2.0 million of deferred revenue was recognized in 2021.

For the nine months ended September 30, 2022, no contract revenue related to the Takeda agreement was recognized. For the nine months ended September 30, 2021, the Company recognized contract revenue related to the Takeda agreement of $2.7 million. There was no deferred revenue as of September 30, 2022 nor December 31, 2021.

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.

Services agreements

In June 2021, Rani LLC entered into a service agreement with ICL effective retrospectively to January 1, 2021, and subsequently amended such agreement in March 2022 (as amended, the "Rani LLC-ICL Service Agreement"), pursuant to which Rani LLC and ICL agreed to provide personnel services to the other upon requests. Under the amendment in March 2022, Rani LLC has a right to occupy certain facilities leased by ICL in Milpitas, California and San Antonio, Texas ("Occupancy Services") for general office, research and development, and light manufacturing. The Rani LLC-ICL Service Agreement has a twelve-month term and will automatically renew for a successive twelve-month periods unless terminated; except that the Occupancy Services in Milpitas, California have an original term until February 2023, with the potential for two annual renewals, subject to approval by the landlord upon a nine months' notice of renewal prior to the end of the lease term, and the Occupancy Services in San Antonio, Texas continue until either party gives six months' notice of termination. Except for the Occupancy Services, Rani LLC or ICL may terminate services under the Rani LLC-ICL Service Agreement upon 60 days' notice to the other party. The Rani LLC-ICL Service Agreement specifies the scope of services to be provided as well as the methods for determining the costs of services. Costs are billed or charged on a monthly basis by ICL or Rani LLC, respectively. In July 2022, the Occupancy Services in Milpitas, California were extended for an additional one year lease term through February 2024.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 318	$ 222	$ 844	$ 377
General and administrative	54	149	170	516
Total	$ 372	$ 371	$ 1,014	$ 893

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

As of September 30, 2022, all of the Company's facilities are owned or leased by an entity affiliated with the Company's Chairman (Note 8). The Company pays for the use of these facilities through its services agreements with ICL.

Financing activity

From inception to the first half of 2017, the Company advanced funds to ICL, and ICL made payments directly to certain vendors on behalf of Rani, Rani has reimbursed ICL for all such payments at cost on a monthly basis.

In March 2021, an outstanding notes receivable balance totaling $1.7 million, including all accrued interest, was fully repaid by ICL.

During 2020 and 2021, a related party of the Company, and its affiliates, purchased 2,100,800 common units of Rani LLC and 7,880,120 Series E Preferred Units of Rani LLC. As part of the Organizational Transactions the common units and Series E Preferred Units were exchanged for 5,277,729 shares of the Company's Class A common stock. In connection with the IPO and subsequent thereto, the same related party purchased an additional 6,458,904 shares of the Company's Class A common stock for total gross proceeds of $71.1 million.

Exclusive License, Intellectual Property and Common Unit Purchase Agreement

The Company, through Rani LLC, and ICL entered into an exclusive license and an intellectual property agreement and common unit purchase agreement in 2012. Pursuant to the common unit purchase agreement, the Company issued 46.0 million common units to ICL in return for rights to exclusive commercialization, development, use and sale of certain products and services related to the RaniPill capsule technology. ICL also granted the Company a fully-paid, royalty-free, sublicensable, exclusive license under the intellectual property made by ICL during the course of providing services to the Company related to the RaniPill capsule technology. Such rights were not recorded on the Company's condensed consolidated balance sheet as the transaction was considered a common control transaction.

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

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

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

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

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

Secondary Sales Transactions

In February 2021, one of the Company's named executive officers and then member of the Board of Managers of Rani LLC, and a current member of the Board of Managers of Rani LLC sold a total of 210,000 common units to a third-party investor at $7.1471 per unit. The Company determined that the sales price was above fair value of such units and as a result recorded equity-based compensation expense of $0.5 million for which $0.2 million was recorded as general and administrative expense and $0.3 million was recorded as research and development expense. The $0.5 million represents the difference between the sales price and fair value of the common units.

Tax Receivable Agreement

Certain parties to the TRA, entered into in August 2021 pursuant to the IPO and Organizational Transactions are related parties of the Company. The TRA provides that the Company pay to such entities and individuals 85% of the amount of tax benefits, if any, it is deemed to realize from exchanges of Paired Interests (Note 2). During the nine months ended September 30, 2022, these parties to the TRA exchanged 2,317,184 Paired Interests that resulted in tax benefits subject to the TRA (Note 14).

Registration Rights Agreement

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

Rani LLC Agreement

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

During the nine months ended September 30, 2022, certain parties to the Rani LLC Agreement exchanged 2,317,184 Paired Interests for an equal number of shares of the Company's Class A common stock.

8. Leases

The Company pays for the use of its office, laboratory and manufacturing facility in San Jose, California as part of the RMS-ICL Service Agreement. In April 2022, RMS assigned the RMS-ICL Service Agreement to Rani LLC. The RMS-ICL Service Agreement has a twelve-month term and will automatically renew for successive twelve-month periods unless Rani LLC or ICL terminate occupancy under the RMS-ICL Service Agreement upon six months' notice. The Company determined it to be reasonably certain that it would exercise its renewal option for a successive twelve-month period and has considered it in the determination of the right-of-use assets and lease liabilities associated with the RMS-ICL Service Agreement as of September 30, 2022.

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

The Company's leases are accounted for as operating leases and require certain fixed payments of real estate taxes and insurance in addition to future minimum lease payments, and certain variable payments of common area maintenance costs and building utilities. Variable lease payments are expensed in the period in which the obligation for those payments is incurred. These variable lease costs are payments that vary in amount beyond the commencement date, for reasons other than passage of time. Total operating lease expense incurred with ICL was $1.1 million and $0.6 million for the nine months ended September 30, 2022 and 2021, respectively. Short term lease expense are included in the total operating lease expense and not immaterial for the periods presented. Variable lease payments are excluded in the total operating lease expense and immaterial for the periods presented.

Supplemental information on the Company's condensed consolidated balance sheet and statements of cash flow as of September 30, 2022 related to leases was as follows (in thousands):

	September 30, 2022
Balance sheet	
Operating lease right-of-use assets	$ 1,302
Operating lease liability, current portion	$ 984
Operating lease liability, less current portion	318
Total operating lease liability	$ 1,302

	September 30, 2022
Cash flows	
Cash paid for amounts included in lease liabilities:	
Operating cash flows used for operating leases	$ 574

	September 30, 2022
Weighted-average remaining lease term	1.4 years
Weighted-average discount rate	6.9%

As of September 30, 2022, minimum annual rental payments under the Company's operating lease agreements are as follows (in thousands):

Year ending December 31,		
2022 (remaining three months)	$	258
2023		1,044
2024		59
Total undiscounted future minimum lease payments	$	1,361
Less: Imputed interest		(59)
Total operating lease liability	$	1,302
Less: Operating lease liability, current portion		984
Operating lease liability, less current portion	$	318

Operating leases in the table above exclude future minimum lease payments for Occupancy Services in San Antonio, Texas under the Rani LLC-ICL Service Agreement. Future minimum lease payments for Occupancy Services in San Antonio for fiscal years 2022 (remaining three months) and 2023 totaled $0.1 million and $0.1 million, respectively.

9. Warrants

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. As of September 30, 2022, there were 76,336 warrants outstanding.

10. Stockholders' Equity / Members' Deficit

Prior to the Organizational Transactions, Rani LLC was authorized to issue 101,000,000 common units, of which 10,850,000 had been reserved for issuance as Profits Interests and 32,620,000 were reserved for six separate classes, the Series A convertible preferred units (the "Series A units"), the Series B convertible preferred units (the "Series B units"), the Series C convertible preferred units (the "Series C units"), the Series C-1 convertible preferred units (the "Series C-1 units"), the Series D convertible preferred units (the "Series D units"), and the Series E convertible preferred units (the "Series E units"), collectively the "Preferred Units".

The members of the Rani LLC who held these common and Preferred Units were not liable, solely by reason of being a member, for the debts, obligations, or liabilities of the Company whether arising in contract or tort; under a judgment, decree, or order of a court; or otherwise. The members were also not obligated to make capital contributions to Rani LLC and Rani LLC would have dissolved only upon a written consent of a majority of the members.

The Company's Profits Interests were subject to either a combination of service, market, or performance vesting conditions. Vested Profits Interests were treated as common units for purposes of distributions.

For the nine months ended September 30, 2022, certain of the Continuing LLC Owners executed an exchange of 4,650,195 Paired Interests and 158,051 non-corresponding Class A Units of Rani LLC in return for an equal number of shares of the Company's Class A common stock. The corresponding shares of the Company's Class B common stock included in the exchange of Paired Interests were subsequently cancelled and retired pursuant to the terms of the Rani LLC Agreement.

In August 2022, the Company entered into a Controlled Equity Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (collectively the "Agents"), pursuant to which the Company may offer and sell from time to time through the Agents up to $150 million of shares of its Class A common stock, in such share amounts as the Company may specify by notice to the Agents, in accordance with the terms and conditions set forth in the Sales Agreement. The potential proceeds from the Sales Agreement are expected to be used for general corporate purposes. As of September 30, 2022, the Company has no sales under the Sales Agreement. In connection with the Sales Agreement, the Company recognized deferred offering costs totaling $0.3 million as a component of prepaid expenses and other current assets in the condensed consolidated balance sheet as of September 30, 2022 which will be offset against proceeds upon a sale under the Sales Agreement within the condensed consolidated statement of changes in stockholders equity.

11. Equity-Based Compensation

Stock Options

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

	Number of Stock Option Awards	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2021	2,300,819	$ 14.12	9.55	$ 976
Granted	1,525,285	$ 12.67	9.52	$ —
Cancelled	(56,135)	$ 16.04		
Balance at September 30, 2022	3,769,969	$ 13.50	9.10	$ 170
Exercisable at September 30, 2022	851,908	$ 13.07	8.88	$ 61
Nonvested at September 30, 2022	2,918,061	$ 13.63	9.16	$ 109

As of September 30, 2022, there was $25.6 million of unrecognized equity-based compensation expense related to stock options which is expected to be recognized over a weighted-average period of approximately 2.7 years.

Restricted Stock Units

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

	Number of Restricted Stock Units	Weighted Average Grant-Date Fair Value per Share
Balance at December 31, 2021	596,500	$ 19.56
Granted	443,400	$ 13.21
Vested	(267,650)	$ 19.56
Forfeited	(86,600)	$ 17.87
Balance at September 30, 2022	685,650	$ 15.67

As of September 30, 2022, there was $9.7 million of unrecognized equity-based compensation expense related to RSUs which is expected to be recognized over a weighted-average period of approximately 2.5 years.

Restricted Stock Awards

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

	Number of Restricted Stock Awards	Weighted Average Grant-Date Fair Value per Share
Balance at December 31, 2021	113,173	$ 6.15
Vested	(33,237)	$ 6.16
Forfeited	(4,548)	$ 6.25
Balance at September 30, 2022	75,388	$ 6.14

As of September 30, 2022, there was $0.2 million of unrecognized equity-based compensation expense related to RSAs which is expected to be recognized over a weighted-average period of approximately 1.2 years. The total fair value of the RSAs that vested in 2022 was approximately $0.5 million.

2021 Employee Stock Purchase Plan

The Company recognized $0.1 million of stock-based compensation expense related to the 2021 Employee Stock Purchase Plan (the "ESPP") during the nine months ended September 30, 2022. There was no stock-based compensation expense related to the ESPP recognized during the nine months ended September 30, 2021. As of September 30, 2022, contributions withheld from employees were $0.2 million and recorded as a component of accrued expenses in the condensed consolidated balance sheet. As of September 30, 2022, total unrecognized compensation costs related to the ESPP were de minimis and will be amortized over a weighted average vesting term of 0.2 years.

Equity-Based Compensation Expense

The following table summarizes the components of equity-based compensation expense resulting from the grant of stock options, RSUs, RSAs, the ESPP, and a secondary sales transaction entered into in February 2021, recorded in the Company's condensed consolidated statement of operations and comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 1,700	6,635	$ 4,586	$ 6,922
General and administrative	2,702	12,061	6,697	12,509
Total equity-based compensation	$ 4,402	18,696	$ 11,283	$ 19,431

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. The Company is currently involved in several opposition proceedings at the European Patent Office, all of which were asserted against it by Novo Nordisk AS. The ultimate outcome of this matter as a loss is not probable nor is there any amount that is reasonably estimable. However, the outcome of the opposition proceedings could impact the Company's ability to commercialize its products in Europe.

Tax Receivable Agreement

The Company is party to a TRA with certain of the Continuing LLC Owners (Note 2). As of September 30, 2022, 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 $20.8 million at September 30, 2022.

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. The remaining $15.0 million of Loans ("Tranche 2") is uncommitted and is subject to certain conditions and approval by the Lender. The purpose of the Loans is for general corporate purposes. In exchange for access to this facility, the Company agreed to issue warrants exercisable into 76,336 shares of the Company's Class A common stock, as may be adjusted for certain anti-dilution adjustments, dividends, stock splits, and reverse stock splits, at an exercise price per share equal to $11.79 (Note 9).

Pursuant to the Loan Agreement, the maturity date for the Loans is August 1, 2026 (the "Maturity Date"). The Loan principal is repayable in equal monthly installments beginning September 2024 extendable to March 2025 under certain conditions. The Loans bear interest at a variable rate per annum equal to the greater of (A) the prime rate, as published by the Wall Street Journal from time to time plus 5.60% or (B) 10.35%. The Loan Agreement is collateralized by substantially all of the Company's assets, in which the Lender is granted continuing security interests. The Loans includes customary events of default, including instances of a material adverse change in the Company's operations, which may require prepayment of the outstanding Loans. At September 30,

2022, the effective interest rate on the Loans was 14.09% and there were no events of default during the nine months ended September 30, 2022.

The Loans contains a contingent interest feature in the event of default that is not clearly and closely related to the underlying note and meets the definition of a derivative. The Company concluded that the fair value of this derivative was insignificant at September 30, 2022.

Pursuant to the Loan Agreement, beginning on the first anniversary of the closing, the Company is subject to a financial covenant that requires the Company to have at least two drug products utilizing its oral delivery technology in clinical development at all times. The financial covenant does not apply if the Company has a market capitalization above $650.0 million. The Loan Agreement also contains various covenants and restrictive provisions that, among other things, limit the Company's ability to (i) incur additional debt, guarantees or liens; (ii) pay any dividends; (iii) enter into certain change of control transactions; (iv) sell, transfer, lease, license, or otherwise dispose of certain assets; (v) make certain investments or loans; and (vi) engage in certain transactions with related persons. As of September 30, 2022, the Company was in compliance with all applicable debt covenants under the Loan Agreement.

As of September 30, 2022, future principal payments for the Company's debt are as follows (in thousands):

Year ending December 31,		
2022 (remaining three months)	$	—
2023		—
2024		2,500
2025		7,500
2026		5,000
Total principal payments	$	15,000
Less: amount representing debt discount		(909)
Total long-term debt	$	14,091

The fair value of the warrants to purchase the Company's Class A common stock issued in connection with the Loan Agreement were estimated on the date of issuance using the Black-Scholes valuation model and recorded to additional paid-in capital. The fair value of the warrants on the date of issuance as well as the debt issuance costs incurred in connection with the entry into the Loan Agreement are presented as a direct deduction from the carrying amount of the term loan on the condensed consolidated balance sheet and are being amortized utilizing the effective interest method over the term of the loan. The Company recorded interest expense for the amortization of the fair value of the warrants and debt issuance costs that were de minimis for the three and nine months ended September 30, 2022.

14. Income Taxes

The Company is the managing member of Rani LLC and, as a result, consolidates the financial results of Rani LLC and its taxable subsidiary RMS in the condensed consolidated financial statements. Rani LLC is a pass-through entity for United States federal and most applicable state and local income tax purposes following the IPO and Organizational Transactions. As an entity classified as a partnership for tax purposes, Rani LLC is not subject to United States federal and certain state and local income taxes. Any taxable income or loss generated by Rani LLC is passed through to, and included in the taxable income or loss of, its members, including the Company. The Company is taxed as a corporation and pays corporate federal, state and local taxes with respect to income allocated to it, based on its economic interest in Rani LLC. The Company's tax provision also includes the activity of RMS, which is taxed as a corporation for United States federal and state income tax purposes.

The Company's effective income tax rate was (0.24)% and (0.21)% for the nine months ended September 30, 2022 and 2021, respectively. As a result of the exchanges for the nine months ended September 30, 2022 (Note 10), the Company recorded a $18.0 million deferred tax asset related to income tax benefit associated with the basis of the net assets of Rani LLC. Because of the Company's history of operating losses, the Company believes that recognition of the deferred tax assets arising from such future income tax benefits is currently not more-likely-than-not to be realized and, accordingly, has recognized a full valuation allowance on its deferred tax assets.

There were no material changes to uncertain tax positions for the nine months ended September 30, 2022 and 2021, and the Company does not anticipate material changes within the next 12 months.

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,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Numerator:				
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.	$ (7,955)	$ (3,142)	$ (21,802)	$ (3,142)
Denominator:				
Weighted average Class A common share outstanding—basic and diluted	24,468	19,437	23,449	19,437
Net loss per Class A common share attributable to Rani Therapeutics Holdings, Inc.—basic and diluted	$ (0.33)	$ (0.16)	$ (0.93)	$ (0.16)

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:

	As of September 30,	
	2022	2021
Paired Interests	24,640,196	29,290,391
Stock options	3,769,969	2,119,524
Non-corresponding Class A Units	1,387,471	1,545,811
Restricted stock units	685,650	597,500
Warrants	76,336	—
Restricted stock awards	75,388	119,915
Shares issuable pursuant to the ESPP	30,558	—
	30,665,568	33,673,141

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, 2022. Therefore, they are not included in the computation of net loss per Class A common share attributable to Rani Holdings.

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

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes 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, 2021, as filed with the Securities and Exchange Commission ("SEC"). Some of the information contained in this discussion and analysis or set forth elsewhere in this document, includes forward looking statements that involve risks, uncertainties, and assumptions. Our actual results could differ materially from those discussed in or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors" in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2021. Please also see the section titled "Forward Looking Statements."

The following discussion contains references to calendar year 2021 and the nine months ended September 30, 2022 and 2021, respectively, which represents the condensed consolidated financial results of Rani Therapeutics Holdings, Inc. (the "Company") and its subsidiaries for the year ended December 31, 2021 and the nine months ended September 30, 2022 and 2021, respectively. Unless we state otherwise or the context otherwise requires, the terms "we," "us," "our," and "Rani" and similar references refers to the Company and its consolidated subsidiaries.

Overview

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

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

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

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

As is common with biotechnology companies, we rely on third-party suppliers for the supply of raw materials and active pharmaceutical ingredients ("APIs") and drug substances required for the production of our product candidates. In addition, we work with third parties to manufacture and develop biologics and drugs for inclusion in the current RaniPill capsule and RaniPill HC. Design work, prototyping and pilot manufacturing are performed in-house, and we have utilized third-party engineering firms to assist with the design of manufacturing lines that support our supply of the current RaniPill capsule and RaniPill HC. Certain of our suppliers of components and materials are single source suppliers. We believe our vertically integrated manufacturing strategy will offer significant advantages, including rapid product iteration, control over our product quality and the ability to rapidly scale our manufacturing capacity. This capability also allows us to develop future generations of products while maintaining the confidentiality of our intellectual property. Our vertically integrated manufacturing strategy will result in material future capital outlays and fixed costs related to constructing and operating a manufacturing facility. We have and plan to continue to invest in automated manufacturing production lines for the current RaniPill capsule and RaniPill HC. Those assets deemed to have an alternative future use have been capitalized as property and equipment while those projects related to our assets determined to not have an alternative future use have been expensed as research and development costs.

Clinical Update

We have begun preclinical development with RT-111, a RaniPill GO capsule containing an ustekinumab biosimilar. The RaniPill GO is the original RaniPill capsule, which has been developed to deliver payloads up to 3mg with high bioavailability.

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

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

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

Following a strategic priority review, we decided not to continue active development of RT-109, a RaniPill capsule containing human growth hormone. We remain open to partnering opportunities with respect to RT-109, but intend to focus internal efforts on our other pipeline programs.

We expect to submit an Investigational New Drug (IND) application for RT-102, followed by Phase 2 initiation in the second half of 2023. We also expect to initiate three additional Phase 1 studies in 2023 with pipeline molecules – RT-105, RT-110 and RT-111. RT-105 is the RaniPill containing an adalimumab biosimilar. RT-110 is the RaniPill containing PTH for hypo-parathyroidism.

Financial Update

In August 2022, we entered into a loan and security agreement and related supplement (the “Loan Agreement”) with Avenue Venture Opportunities Fund, L.P (the “Lender”). The Loan Agreement provides for term loans (the “Loans”) in an aggregate principal amount up to $45.0 million. A Loan of $30.0 million was committed at closing, with $15.0 million funded immediately and $15.0 million available to be drawn between October 1, 2022 and December 31, 2022. The remaining $15.0 million of Loans is uncommitted and is subject to certain conditions and approval by the Lender. The purpose of the Loans is for general corporate purposes. The Loan Agreement also contains various covenants and restrictive provisions. As of September 30, 2022, we were in compliance with all applicable debt covenants under the Loan Agreement and had cash, cash equivalents, restricted cash and marketable securities totaling $98.7 million.

In August 2022, we entered into a Controlled EquitySM Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (collectively, the “Agents”), pursuant to which we may offer and sell from time to time through the Agents up to $150 million of shares of our Class A common stock, in such share amounts as we may specify by notice to the Agents, in accordance with the terms and conditions set forth in the Sales Agreement. As of September 30, 2022, we had not delivered any placement notices to either of the Agents.

COVID-19 Business Impact

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. We believe that, as a result of the COVID-19 pandemic, we have experienced delays due to the unavailability of vendors or delays in their availability with respect to research and development activities due to high demand or disruption to their business, delays in certain shipments of materials for our manufacturing, increases in prices charged by third parties for goods and services due to additional processes or costs resulting from COVID-19 procedures, disruption to travel which affects our ability to establish and maintain business relationships, and disruption to employee work schedules. While we have not experienced material impacts through September 30, 2022, the extent to which the COVID-19 pandemic will further directly or indirectly impact our results of operation and financial condition has been and will continue to be driven by many factors, most of which are beyond our control and ability to forecast. Because of these uncertainties, we cannot estimate how long or to what extent COVID-19 will impact our operations.

Organizational Transactions

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

Rani LLC has been, and after the IPO continues to be, treated as a pass-through entity for U.S. federal and state income tax purposes and accordingly has not been subject to U.S. federal or state income tax. The wholly owned subsidiary of Rani LLC, Rani Management Services, Inc. (“RMS”), which was incorporated in 2019, is taxed as a corporation for U.S. federal and most applicable state, local income tax and foreign tax purposes. As a result of its ownership of interests in Rani LLC ("LLC Interests"), the Company is subject to U.S. federal, state and local income taxes with respect to its allocable share of any taxable income of Rani LLC and will be taxed at the prevailing corporate tax rates. In addition to tax expenses, we also incur expenses related to our operations and may be required to make payments under the Tax Receivable Agreement with certain of the individuals and entities that continue to hold interests in Rani LLC after the IPO (the "Continuing LLC Owners"). The Continuing LLC Owners are entitled to exchange, subject to the terms of the Rani LLC Agreement, the Class A Units they hold in Rani LLC, together with the shares they hold of our Class B common stock (together referred to as a "Paired Interest"), in return for shares of our Class A common stock on a one-for-one basis provided that, at our election, we may effect a direct exchange of such Class A common stock or make a cash payment equal to a volume weighted average market price of one share of Class A common stock for each Paired Interest redeemed. Any shares of Class B common stock will be cancelled on a one-for-one basis if, at the election of the Continuing LLC Owners, we redeem or exchange such Paired Interest pursuant to the terms of the Rani LLC Agreement. These exchanges and redemptions may result in increases in the tax basis of the assets of Rani LLC that otherwise would not have been available. Increases in tax basis resulting from such exchanges may reduce the amount of income tax that the Company would otherwise be required to pay in the future. This tax basis may also decrease the gains (or increase the losses) on future dispositions of certain assets to the extent tax basis is allocated to those assets. Due to the uncertainty of various factors, we cannot estimate the likely tax benefits we will realize as a result of exchanges, and the resulting amounts we will likely pay out to the Continuing LLC Owners pursuant to the Tax Receivable Agreement; however, we estimate that such payments may be substantial in the event we are profitable. Certain individuals who continue to own interests in Rani LLC but do not hold shares of the Company’s Class B common stock (“non-corresponding Class A Units”) have the ability to exchange their non-corresponding Class A Units of Rani LLC for 1,387,471 shares of the Company’s Class A common stock.

Components of Results of Operations

Contract Revenue

To date, we have not generated any revenue from commercial product sales and do not expect to generate any revenue from the sale of commercial products in the foreseeable future. Our only revenue to date has been derived from evaluation agreements, which has been recorded as contract revenue. As of September 30, 2022, we had no active evaluation agreements, and therefore we expect that our revenue for the next several years will be derived from any new agreements that may be executed in the future.

Our ability to generate commercial product revenue and to become profitable will depend upon our ability to successfully develop, obtain regulatory approval for and commercialize the RaniPill capsule and RaniPill HC. Because of the numerous risks and uncertainties associated with product development, regulatory approval and commercialization, we are unable to predict the amount, timing or whether we will be able to generate any commercial product revenue.

Operating Expenses

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

Research and Development Expense

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

External expenses, consisting of:

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

Internal expenses, consisting of:

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

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

Costs of property and equipment related to scaling-up our manufacturing capacity for clinical trials and to support commercialization are capitalized as property and equipment unless the related asset does not have an alternative future use. The historical focus of our research and development has been on the RaniPill delivery platform and not tracked costs on a project-by-project basis associated with different drug compounds.

At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, the RaniPill capsule and RaniPill HC. We expect our research and development expenses to increase significantly in the foreseeable future as we continue to invest in activities related to testing and developing the RaniPill capsule and RaniPill HC, as our product candidates advance into later stages of development, as we begin to conduct larger clinical trials, as we seek regulatory approvals for the RaniPill capsule and RaniPill HC upon successful completion of clinical trials, and incur expenses associated with hiring additional personnel to support the research and development efforts. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, the successful development of the RaniPill capsule and RaniPill HC is highly uncertain, and we may never succeed in achieving regulatory approval for the RaniPill capsule and RaniPill HC.

General and Administrative Expenses

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

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

Other Income (Expense), Net

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

Non-Controlling Interest

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

In August 2021, based on the Organizational Transactions, the Company became the sole managing member of Rani LLC. As of September 30, 2022, the Company held approximately 49% of the Class A Units of Rani LLC, and approximately 51% of the outstanding Class A Units of Rani LLC are held by the Continuing LLC Owners. Therefore, we report NCI based on the Class A Units of Rani LLC held by the Continuing LLC Owners on our condensed consolidated balance sheet as of September 30, 2022. Income or loss attributed to the NCI in Rani LLC is based on the Class A Units outstanding during the period for which the income or loss is generated and is presented on the condensed consolidated statements of operations and comprehensive income or loss.

Future exchanges of Paired Interests and non-corresponding Class A Units of Rani LLC will result in a change in ownership and reduce or increase the amount recorded as NCI and increase or decrease additional paid-in-capital when Rani LLC has positive or negative net assets, respectively. From the date of the Organizational Transactions to September 30, 2022, there were 4,650,195 exchanges of Paired Interests and 158,051 exchanges of non-corresponding Class A Units of Rani LLC for an equal number of shares of our Class A common stock.

Tax Receivable Agreement

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

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

Relationship with InCube Labs, LLC

Services Agreements

In June 2021, Rani LLC entered into a service agreement with InCube Labs, LLC (“ICL”) effective retrospectively to January 1, 2021, and subsequently amended such agreement in March 2022 (as amended, the "Rani LLC-ICL Service Agreement"), pursuant to which Rani LLC and ICL agreed to provide personnel services to the other upon requests. Under the amendment in March 2022, Rani LLC has a right to occupy certain facilities leased by ICL in Milpitas, California and San Antonio, Texas (“Occupancy Services”) for general office, research and development, and light manufacturing. The Rani LLC-ICL Service Agreement has a twelve-month term and will automatically renew for a successive twelve-month periods unless terminated; except that the Occupancy Services in Milpitas, California have a term until February 2023, with the potential for two annual renewals, subject to approval by the landlord upon a nine months’ notice of renewal prior to the end of the lease term, and the Occupancy Services in San Antonio, Texas continue until either party gives six months’ notice of termination. Except for the Occupancy Services, Rani LLC or ICL may terminate services under the Rani LLC-ICL Service Agreement upon 60 days' notice to the other party. The Rani LLC-ICL Service Agreement specifies the scope of services to be provided as well as the methods for determining the costs of services. Costs are billed

or charged on a monthly basis by ICL or Rani LLC, respectively. In July 2022, the Occupancy Services in Milpitas, California were extended for an additional one year lease term through February 2024.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	$ 318	$ 222	$ 844	$ 377
General and administrative	54	149	170	516
Total	$ 372	$ 371	$ 1,014	$ 893

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

As of September 30, 2022, all of our facilities are owned or leased by an entity affiliated with our Chairman. Rani LLC pays for the use of these facilities through our services agreements with ICL.

Financing activity

In March 2021, an outstanding notes receivable balance totaling $1.7 million, including all accrued interest, was fully repaid by ICL.

Exclusive License Agreement

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

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

In June 2021, we entered into the Non-Exclusive License Agreement with ICL, pursuant to which we granted ICL a non-exclusive, fully-paid license under specified patents that were assigned from ICL to us. Additionally, we agreed not to license these patents to a third party in a specific field outside the field of oral delivery of sensors, small molecule drugs or biologic drugs including, any peptide, antibody, protein, cell therapy, gene therapy or vaccine, if ICL can prove that it or its sublicensee has been in active

development of a product covered by such patents in that specific field. ICL may grant sublicenses under this license to third parties only with our prior approval. The Non-Exclusive License Agreement will continue in perpetuity unless terminated.

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

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

Tax Receivable Agreement

ICL is party to the TRA, entered into in August 2021 pursuant to the IPO and Organizational Transactions. The TRA provides that we pay to such entities and individuals 85% of the amount of tax benefits, if any, it is deemed to realize from exchanges of Paired Interests. During the nine months ended September 30, 2022, these parties to the TRA exchanged 2,317,184 Paired Interests that resulted in tax benefits subject to the TRA.

Registration Rights Agreement

In connection with the IPO, we entered into a Registration Rights Agreement with the Continuing LLC Owners, including ICL. The Registration Rights Agreement provides the Continuing LLC Owners certain registration rights whereby, at any time following the IPO and the expiration of any related lock-up period, the Continuing LLC Owners can require us to register under the Securities Act shares of Class A common stock issuable to them upon, at our election, redemption or exchange of their LLC Interests. The Registration Rights Agreement also provides for piggyback registration rights for the Continuing LLC Owners.

Rani LLC Agreement

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

During the nine months ended September 30, 2022, these parties to the Rani LLC Agreement exchanged 2,317,184 Paired Interests for the Company's Class A common stock.

Results of Operations

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

Comparison of the three months ended September 30, 2022 and 2021

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

	Three Months Ended September 30,		
	2022	2021	Change
Operating expenses			
Research and development	$ 9,103	$ 11,959	(23.9) %
General and administrative	7,239	15,822	(54.2)
Total operating expenses	$ 16,342	$ 27,781	(41.2) %
Loss from operations	(16,342)	(27,781)	(41.2)
Other income (expense), net			
Interest income and other, net	379	13	2,815.4
Loss on extinguishment of debt	—	(700)	*
Interest expense and other, net	(352)	(110)	220.0
Change in estimated fair value of preferred unit warrant	—	(85)	*
Loss before income taxes	(16,315)	(28,663)	(43.1)
Income tax expense	107	(37)	(389.2)
Net loss	$ (16,208)	$ (28,700)	(43.5) %
Net loss attributable to non-controlling interest	(8,253)	(25,558)	(67.7)
Net loss attributable to Rani Therapeutics Holdings, Inc.	$ (7,955)	$ (3,142)	153.2 %

* No comparable result in the period

Research and Development Expenses

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

	Three Months Ended September 30,	
	2022	2021
Payroll, equity-based compensation and related benefits	$ 6,792	$ 10,039
Facilities, materials and supplies	1,475	1,005
Third-party services	779	812
Other	57	103
Total	$ 9,103	$ 11,959

Research and development expenses were $9.1 million for the three months ended September 30, 2022, compared to $12.0 million for the three months ended September 30, 2021. The difference was primarily attributed to a decrease of $4.9 million in equity-based compensation due to our non-recurring IPO and Organizational Transactions in the three months ended September 30, 2021, partially offset by an increase of $1.7 million in salaries and related benefit costs due to higher headcount, and an increase in facilities, materials and supplies expenses of $0.5 million.

General and Administrative Expenses

General and administrative expenses were $7.2 million for the three months ended September 30, 2022, compared to $15.8 million for the three months ended September 30, 2021. The difference was primarily attributed to a decrease of $9.4 million in equity-based compensation due to our non-recurring IPO and Organizational Transactions in the three months ended September 30, 2021, partially offset by an increase of $0.4 million in salaries and related benefit costs due to higher headcount, and an increase of $0.4 million in third-party services and other costs.

Other Income (Expense), Net

Other income, net, was $0.1 million for the three months ended September 30, 2022, compared to other expense, net, of $0.9 million for the three months ended September 30, 2021. The difference was primarily attributed to an increase in interest income of $0.4 million from our investment in marketable securities, a decrease of $0.7 million from loss on extinguishment of debt and a decrease of $0.1 million from change in estimated fair value of preferred unit warrants offset by an increase in interest expense of $0.2 million from our long-term debt.

Comparison of the nine months ended September 30, 2022 and 2021

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

	Nine Months Ended September 30,			
	2022	2021	Change	
Contract revenue	$ —	$ 2,717	*	%
Operating expenses				
Research and development	26,221	19,065	37.5	
General and administrative	19,748	21,889	(9.8)	
Total operating expenses	$ 45,969	$ 40,954	12.2	%
Loss from operations	(45,969)	(38,237)	20.2	
Other income (expense), net				
Interest income and other, net	430	73	489.0	
Loss on extinguishment of debt	—	(700)	*	
Interest expense and other, net	(352)	(467)	(24.6)	
Change in estimated fair value of preferred unit warrant	—	(371)	*	
Loss before income taxes	(45,891)	(39,702)	15.6	
Income tax expense	(111)	(81)	37.0	
Net loss	$ (46,002)	$ (39,783)	15.6	%
Net loss attributable to non-controlling interest	(24,200)	(36,641)	(34.0)	
Net loss attributable to Rani Therapeutics Holdings, Inc.	$ (21,802)	$ (3,142)	593.9	%

* No comparable result in the period

Contract Revenue

For the nine months ended September 30, 2022, the Company had no contract revenue. For nine months ended September 30, 2021, the Company recognized contract revenue related to the Takeda agreement of $2.7 million.

Research and Development Expenses

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

	Nine Months Ended September 30,	
	2022	2021
Payroll, equity-based compensation and related benefits	$ 18,421	$ 15,139
Facilities, materials and supplies	3,983	2,541
Third-party services	3,513	1,172
Other	304	213
Total	$ 26,221	$ 19,065

Research and development expenses were $26.2 million for the nine months ended September 30, 2022, compared to $19.1 million for the nine months ended September 30, 2021. The difference was primarily attributed to a decrease of $2.3 million in equity-based compensation due to our non-recurring IPO and Organizational Transactions in the three months ended September 30, 2021, offset by an increase of $5.6 million in salaries and related benefit costs due to higher headcount, an increase in third-party services of $2.3 million associated with the Company's preclinical and clinical studies, and an increase in facilities, materials and supplies and other costs of $1.6 million.

General and Administrative Expenses

General and administrative expenses were $19.7 million for the nine months ended September 30, 2022, compared to $21.9 million for the nine months ended September 30, 2021. The difference was primarily attributed to a decrease of $5.8 million in equity-based compensation and third-party services of $0.2 million due to our non-recurring IPO and Organizational Transactions in the three months ended September 30, 2021, partially offset by an increase of $2.0 million in salaries and related benefit costs due to higher headcount, an increase in facility costs of $1.3 million and an increase in other costs of $0.6 million due to increase in travel after pandemic-induced lockdowns lifted.

Other Income (Expense), Net

Other income, net, was $0.1 million for the nine months ended September 30, 2022, compared to other expense, net, of $1.5 million for the nine months ended September 30, 2021. The difference was primarily attributed to an increase in interest income of $0.4 million from our investment in marketable securities, a decrease of $0.7 million from loss on extinguishment of debt and a decrease of $0.4 million from change in estimated fair value of preferred unit warrants, partially offset by an increase in interest expense of $0.2 million from our long-term debt.

Liquidity and Capital Resources

Source of Liquidity

We have not generated any revenue from commercial product sales and have incurred significant operating losses and negative cash flows from operations. We have not yet commercialized any products, and we do not expect to generate revenue from sales of commercial products for several years, if at all. We anticipate that we will continue to incur net losses for the foreseeable future. Since our inception, we have devoted substantially all of our resources on organizing and staffing our company, business planning, research and development activities, including the RaniPill platform design, drug formulation, preclinical studies, clinical trials, manufacturing automation and scale up, establishing our intellectual property portfolio, and providing general and administrative support for these operations. To date, we have financed our operations primarily through an IPO, private placements of Rani LLC preferred units, the issuance of convertible promissory notes, and long-term debt, as well as contract revenue generated from evaluation agreements. In August 2021, we raised net proceeds of $73.6 million from the IPO.

In August 2022, we entered into the Loan Agreement with the Lender. The Loan Agreement provides for Loans in an aggregate principal amount up to $45.0 million. A Loan of $30.0 million was committed at closing, with $15.0 million funded immediately and $15.0 million available to be drawn between October 1, 2022 and December 31, 2022. The remaining $15.0 million of Loans is uncommitted and is subject to certain conditions and approval by the Lender. The purpose of the Loans is for general corporate purposes. The Loan Agreement also contains various covenants and restrictive provisions. As of September 30, 2022, we were in compliance with all applicable debt covenants under the Loan Agreement and had cash, cash equivalents, restricted cash and marketable securities totaling $98.7 million.

In August 2022, we entered into the Sales Agreement with the Agents, pursuant to which we may offer and sell from time to time through the Agents up to $150 million of shares of our Class A common stock, in such share amounts as we may specify by notice to the Agents, in accordance with the terms and conditions set forth in the Sales Agreement. Upon delivery of a placement notice to one of the Agents and subject to the terms and conditions of the Sales Agreement, sales of the shares may be made by any method permitted by law deemed to be “at the market offerings” as defined in Rule 415(a)(4) under the Securities Act, including sales made directly on the Nasdaq Stock Market or in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices and/or any other method permitted by law. Under the Sales Agreement, we will set the parameters for the sale of the shares, including the number of shares to be issued, the time period during which sales are requested to be made, any limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. We are not obligated to sell any shares under the Sales Agreement. As of September 30, 2022, we had not delivered any placement notices to either of the Agents.

Since our inception, we have incurred significant losses and negative cash flows from operations. Our net losses were $46.0 million and $39.8 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of $30.2 million. We expect to continue to incur significant losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities. Until such time as we can generate sufficient revenue from commercial product sales, if ever, we expect to finance our operations through a combination of equity offerings and debt financings, which may include ATM Sales, or other capital sources, which may include strategic collaborations or other arrangements with third parties. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. If we are unable to raise capital or enter into such

agreements as and when needed, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. Insufficient liquidity may also require us to relinquish rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose.

Tax Receivable Agreement

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

As of September 30, 2022, we have not recorded a liability under the TRA related to the income tax benefits originating from the exchanges of Paired Interest or non-corresponding Class A Units of Rani LLC as it is not probable that the Company will realize such tax benefits. To the extent the Company is able to realize the income tax benefits associated with the exchanges of Paired Interest or non-corresponding Class A Units of Rani LLC subject to the TRA, the TRA payable would range from zero to $20.8 million at September 30, 2022.

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

Future Funding Requirements

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

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

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

- the progress, costs, trial design, results of and timing of our preclinical studies and clinical trials;
- the progress, costs, and results of our research pipeline;
- the willingness of the U.S. Food and Drug Administration (“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 the RaniPill capsule and RaniPill HC for various indications;

- the outcome, costs, and timing of seeking and obtaining FDA, and any other regulatory approvals;
- the number and characteristics of product candidates that we pursue;
- our ability to manufacture sufficient quantities of the RaniPill capsules;
- our need to expand our research and development activities;
- the costs associated with manufacturing our product candidates, including establishing commercial supplies and sales, marketing, and distribution capabilities;
- the costs associated with securing and establishing commercial infrastructure;
- the costs of acquiring, licensing, or investing in businesses, product candidates, and technologies;
- our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense, and enforcement of any patents or other intellectual property rights;
- our need and ability to retain key management and hire scientific, technical, business, and engineering personnel;
- the effect of competing drugs and product candidates and other market developments;
- the timing, receipt, and amount of sales from our potential products, if approved;
- our ability to establish strategic collaborations;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- security breaches, data losses or other disruptions affecting our information systems;
- the economic and other terms, timing of and success of any collaboration, licensing, or other arrangements which we may enter in the future; and
- the effects of disruptions to and volatility in the credit and financial markets in the United States and worldwide from the COVID-19 pandemic.

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. 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 in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

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

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 27,219	$ 117,453
Restricted cash equivalents	500	—
Marketable securities	70,952	—
Total cash, cash equivalents, restricted cash equivalents and marketable securities	$ 98,671	$ 117,453

As of September 30, 2022, we had cash, cash equivalents and marketable securities of $98.7 million, compared to $117.5 million as of December 31, 2021. We believe our cash, cash equivalents, restricted cash equivalent and marketable securities will be

sufficient to meet our anticipated operating requirements for at least the next 12 months following the date of issuance of these condensed consolidated financial statements.

Cash Flows

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

	For the Nine Months Ended September 30,	
	2022	2021
Net cash used in operating activities	$ (31,886)	$ (20,796)
Net cash used in investing activities	(71,979)	(235)
Net cash provided by financing activities	14,131	77,716
Net (decrease) increase in cash, cash equivalents and restricted cash equivalents	$ (89,734)	$ 56,685

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2022 was $31.9 million, which was primarily attributable to a net loss of $46.0 million, partially offset by the equity-based compensation expense of $11.3 million, non-cash operating lease expense of $0.5 million and non-cash depreciation and amortization expense of $0.4 million. Additionally, there was an increase in accounts payable of $0.4 million and accrued expenses of $2.5 million attributable to accrued bonuses.

Net cash used in operating activities for the nine months ended September 30, 2021 was $20.8 million, which was primarily attributable to a net loss of $39.8 million, partially offset by the equity-based compensation expense of $19.4 million, loss on the extinguishment of the debt of $0.7 million, non-cash depreciation and amortization of $0.4 million, and change in the estimated fair value of our preferred unit warrant liability of $0.4 million. Additionally there was an increase of $2.5 million in prepaid expenses and other assets, a decrease in accrued expenses of $2.3 million, and a decrease in deferred revenue of $2.7 million.

Investing Activities

For the nine months ended September 30, 2022, net cash used in investing activities was $72.0 million consisting of $70.9 million in purchases of marketable securities and $1.1 million in purchases of property and equipment.

For the nine months ended September 30, 2021, net cash used in investing activities was $0.2 million, consisting solely of purchases of property and equipment.

Financing Activities

For the nine months ended September 30, 2022, net cash provided by financing activities was $14.1 million, which was primarily attributable to proceeds from the issuance of long-term debt and warrants, net of issuance costs of $14.7 million and proceeds from employee stock purchase plan of $0.2 million. These items were partially offset by a $0.6 million decrease for employee taxes paid on net share settlement on the vesting of restricted stock units and payment of deferred financing costs of $0.1 million.

For the nine months ended September 30, 2021, cash provided by financing activities was approximately $77.7 million, consisting of the proceeds from the issuance of Class A common stock sold in the IPO for net proceeds of $74.2 million, the sale and issuance of 884,276 units of our Series E Preferred Units for net proceeds of $6.3 million, and $1.7 million of principal payments received from our related party notes receivable, partially offset by repayment of a paycheck protection program loan of $1.3 million and repayment of a convertible loan of $3.3 million.

Contractual Obligations and Other Commitments

The following table summarizes our contractual obligations and commitments as of September 30, 2022 (in thousands):

	As of September 30,		
	Total	Short-term	Long-term
Operating leases (1)	$ 1,471	$ 1,150	$ 321
Debt obligations (2)	15,825	—	15,825
Total	$ 17,296	$ 1,150	$ 16,146

(1) Represents operating lease payments. See Note 8 to the condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

(2) Represents long-term debt principal maturities and final payment equal to 5.5% of aggregate amount funded, excluding interest. See Note 13 to the condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

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

Critical Accounting Policies and Estimates

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

For further information on our significant accounting policies, refer to our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 31, 2022. Except as noted below, there have been no material changes to our critical accounting policies or estimates from those set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Warrants

We account for equity classified warrants, issued in connection with the Loan Agreement, estimated on the date of issuance using the Black-Scholes valuation model which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield. Such assumptions represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Recently Adopted Accounting Standards

For a description of the expected impact of recent accounting pronouncements, 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.

Other Information

JOBS Act Accounting Election

We are an "emerging growth company" within the meaning of the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). The JOBS Act permits an emerging growth company like us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are electing to use this extended transition period and we will therefore comply with new or revised accounting standards on the earlier of (i) when they apply to private

companies; or (ii) when we lose our emerging growth company status. As a result, our financial statements may not be comparable with companies that comply with public company effective dates for accounting standards. We also rely on other exemptions provided by the JOBS Act, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act unless we cease to be an emerging growth company.

We will remain an emerging growth company until the earliest of (1) December 31, 2026 (the last day of the fiscal year following the fifth anniversary of the closing of our initial public offering), (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 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, 2022.

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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Other than as described below, management believes that there have been no significant changes to the risk factors associated with our business as compared to those disclosed in Part 1, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2021, which is incorporated by reference herein.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We are an early clinical stage biopharmaceutical company with no approved products and no historical commercial product revenue, which makes it difficult to assess our future prospects and financial results.

We are an early clinical stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. Biologics development, especially as it relates to biologic-device combination products, is a highly speculative undertaking and involves a substantial degree of uncertainty. Our operations to date have been limited to developing our technology and undertaking preclinical studies and early clinical trials of our product candidates, which consist of investigational biologics delivered via the RaniPill capsule. We are in early clinical development with a limited number of product candidates, and are in preclinical development with other product candidates. As an early clinical stage company, we have not yet demonstrated an ability to generate revenue or successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields such as biologics development and delivery. Consequently, the ability to accurately assess our future operating results or business prospects is significantly more limited than if we had a longer operating history or approved products on the market.

We expect that our financial condition and operating results will fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control, including, but not limited to:

- the clinical outcomes from the continued development of our product candidates;
- occurrence of adverse events or serious adverse events in preclinical studies or clinical trials of our product candidates;
- potential side effects of our product candidates, whether caused by the biologic formulation or the RaniPill capsule, that could delay or prevent approval or cause an approved product to be taken off the market;
- our ability to obtain, as well as the timeliness of obtaining, additional funding to develop, and potentially manufacture and commercialize our product candidates;
- our ability to manufacture our product candidates to our specifications and in a timely manner to support our preclinical studies and clinical trials, and, if approved, commercialization;
- our ability to scale, optimize and expand automation of our manufacturing processes for our product candidates for the conduct of preclinical studies and clinical trials and, if approved, for successful commercialization;
- competition from existing products directed against the same biologic target or therapeutic indications of our product candidates as well as new products that may receive marketing approval;
- the timing of regulatory review and approval of our product candidates;
- market acceptance of our product candidates that receive regulatory approval, if any, including perception of the safety and efficacy of the oral delivery of biologics;
- our ability to expand our commercial reach by selectively entering into strategic partnerships on favorable terms or at all;
- our ability to establish an effective sales and marketing infrastructure directly or through collaborations with third parties;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;

- our ability to manufacture our product candidates in accordance with current Good Manufacturing Practices (cGMP), for the conduct of preclinical studies and clinical trials and, if approved, for successful commercialization;
- our ability as well as the ability of any third-party collaborators, to obtain, maintain and protect intellectual property rights covering our product candidates and technologies, and our ability to develop, manufacture and commercialize our product candidates without infringing on the intellectual property rights of others;
- our ability to add infrastructure and adequately manage our future growth; and
- our ability to attract and retain key personnel with appropriate expertise and experience to manage our business effectively.

Accordingly, the likelihood of our success must be evaluated in light of many potential challenges and variables associated with a clinical stage biopharmaceutical company, many of which are outside of our control, and past results, including operating or financial results, should not be relied on as an indication of future results.

If we are unable to raise additional capital when needed on acceptable terms, we may be forced to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.

Our operations have consumed substantial amounts of cash since our inception. We are in early clinical development with certain product candidates and have conducted or are in the process of conducting preclinical studies with other product candidates. We intend to advance our product candidates into initial and later stages of clinical development, which requires significant capital. In addition, we are developing the RaniPill HC and intend to evaluate the safety of the RaniPill capsule, independent of any biologic. Developing biologic product candidates, including conducting preclinical studies and clinical trials, and developing the RaniPill platform, is expensive. We will require substantial additional future capital in order to complete the development of the RaniPill platform, expand our manufacturing capabilities, and seek regulatory approval thereof, and to complete the clinical development of our intended product candidates and, if we are successful, to commercialize any of our current product candidates. If the U.S. Food and Drug Administration (FDA) or any comparable foreign regulatory authorities, such as the European Medicines Agency (EMA), require that we perform studies or trials in addition to those that we currently anticipate with respect to the development of our product candidates or any of our future product candidates, or repeat studies or trials, our expenses would further increase beyond what we currently expect, and any delay resulting from such further or repeat studies or trials could also result in the need for additional financing.

Based on our current operating plan, we estimate that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next 12 months. This period could be shortened if there are any significant increases beyond our expectations in spending on development programs or more rapid progress of development programs than anticipated. Our existing capital resources, including the net proceeds from our IPO and Loans, will not be sufficient to enable us to initiate any pivotal clinical trials. Accordingly, we expect that 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.

Our funding requirements and the timing of our need for additional capital are subject to change based on a number of 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 progress and costs of development of the RaniPill HC device and other improvements or advancements to our delivery technologies;
- 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 preclinical studies and clinical trials and other work, as the basis for review and approval of our product candidates;
- 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 capsule;
- our need to expand our research and development activities;

- the costs associated with manufacturing, and obtaining drug supply for, our product candidates, including for clinical and commercial supplies;
- the costs associated with securing and establishing commercial infrastructure, including establishing sales, marketing, and distribution capabilities;
- 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;
- the economic and other terms, timing of and success of any collaboration, licensing, or other arrangements which we may enter in the future; and
- the effects of disruptions to and volatility in the credit and financial markets in the United States and worldwide from the COVID-19 pandemic, the conflict between Ukraine and Russia or other such disruptions.

Additional funding may not be available to us on acceptable terms, or at all. As a result of the COVID-19 pandemic and actions taken to slow its spread as well as the conflict between Ukraine and Russia, inflation, rising interest rates and other conditions, the global credit and financial markets have experienced volatility and disruptions. If we are unable to obtain additional funding from equity offerings or debt financings, including on a timely basis, we may be required to:

- seek collaborators for one or more of our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail one or more of our research or development programs or cease operations altogether.

Conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Our existing indebtedness contains restrictions that limit our flexibility in operating our business. In addition, we may be required to make a prepayment or repay our outstanding indebtedness earlier than we expect.

In August 2022, we entered into the Loan Agreement with the Lender, which provides for Loans in an aggregate principal amount up to $45.0 million. A Loan of $30.0 million was committed at closing, with $15.0 million funded immediately and $15.0 million available to be drawn between October 1, 2022 and December 31, 2022. The remaining $15.0 million of Loans is uncommitted and is subject to certain conditions and approval by the Lender. The Loan Agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- incur or assume certain debt;
- merge or consolidate or acquire all or substantially all of the capital stock or property of another entity;

- enter into any transaction or series of related transactions that would be deemed to result in a change in control of us under the terms of the agreement;
- change the nature of our business;
- change our organizational structure or type;
- license, transfer, or dispose of certain assets;
- grant certain types of liens on our assets;
- make certain investments;
- pay cash dividends; and
- enter into material transactions with affiliates.

The restrictive covenants in the Loan Agreement could prevent us from pursuing business opportunities that we or our stockholders may consider beneficial.

A breach of any of these covenants could result in an event of default under the Loan Agreement. An event of default will also occur if, among other things, a material adverse effect in our business, operations, or condition occurs, which could potentially include a material impairment of the prospect of our repayment of any portion of the amounts we owe under the Loan Agreement. In the case of a continuing event of default under the Loan Agreement, the Lender could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted the Lender a security interest under the Loan Agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the Loan Agreement are secured by substantially all of our existing and future assets, including intellectual property.

At closing, we drew on $15.0 million of the $30.0 million available to us as part of the first tranche. The Loan Agreement also gives us the ability to access an additional $15.0 million, which may be drawn in an additional tranche with the approval of the Lender and subject to the other terms and conditions set forth in the Loan Agreement. If we are unable to satisfy these or other required conditions, or if the Lender does not consent, as applicable, we would not be able to draw down the remaining tranche of financing and may not be able to obtain alternative financing on commercially reasonable terms or at all, which could adversely impact our business.

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay or refinance our indebtedness at the time any such repayment is required. In such an event, we may be required to delay, limit, reduce, or terminate our product development or commercialization efforts. Our business, financial condition, and results of operations could be materially adversely affected as a result.

Risks Related to the Development and Regulatory Approval of Our Product Candidates

We are early in our development efforts and have only a limited number of product candidates in early clinical development, and our other product candidates are still in preclinical development. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are in the early stages of our development efforts and have only a limited number of product candidates in early clinical development. Other product candidates are still in the formulation and preclinical stages. We will need to progress our product candidates through Investigational New Drug (IND)-enabling studies and submit INDs to the FDA or equivalent regulatory filings to foreign regulatory authorities prior to initiating their clinical development. None of our product candidates have advanced into a pivotal study.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful enrollment in clinical trials and completion of preclinical studies and clinical trials with favorable results;
- acceptance of INDs by the FDA or similar regulatory filings by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- demonstrating safety and efficacy to the satisfaction of applicable regulatory authorities;

- receipt of marketing approvals from applicable regulatory authorities, including Biologic License Applications (BLAs) or New Drug Applications (NDAs), from the FDA, and maintaining such approvals;
- establishing clinical and commercial manufacturing capabilities, and securing adequate supply of drugs for our product candidates;
- expanding automation of our manufacturing machinery and procedures;
- establishing and maintaining multiple suppliers for our critical manufacturing materials;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- establishing and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- maintaining an acceptable safety profile and shelf life of our products following approval;
- the class of drugs that are included in our product candidates continuing to represent the standard-of-care for the respective disease target and continuing to have a long-term favorable safety profile; and
- maintaining and growing an organization of people who can develop our products and technology.

The success of our business, including our ability to finance our company and generate any revenue in the future, will depend on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. We may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. We may not be able to successfully deliver the biologic payload to the intestinal wall with great enough certainty to achieve adequate efficacy or safety for any of our product candidates or to the satisfaction of the FDA or other regulatory bodies. Given our early stage of development, it may be several years, if at all, before we have demonstrated the safety and efficacy of a treatment sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. The results of preclinical studies and early clinical trials of our product candidates and studies and trials of other products may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. For example, the results generated to date in preclinical studies and the Phase 1 clinical trials of RT-101 and RT-102 do not ensure that future Phase 2 or later clinical trials of these product candidates will have similar results or be successful. In the Phase 1 clinical trials of RT-101 and RT-102, we tested the RaniPill capsule in a limited number of healthy volunteers. While we have not observed any serious adverse events as a result of these clinical trials, we have not widely tested the RaniPill capsule in humans and cannot be certain how the RaniPill capsule will perform when more widely tested in humans in any later clinical trials. In addition to our ongoing and planned preclinical studies and clinical trials, we expect to have to complete at least two large scale, or adequate, well-controlled trials to demonstrate substantial evidence of efficacy and safety for each product candidate we intend to commercialize. Further, given the patient populations for which we are developing biologics, we expect to have to evaluate long-term exposure to establish the safety of our biologics in a chronic dose setting.

Clinical trial failures may result from a multitude of factors including, but not limited to, flaws in trial design, dose and formulation selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety and/or efficacy traits of the product candidate. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials.

We may experience delays in ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approvals to commence a clinical trial;
- fraud or negligence on the part of consultants or contractors;

- obtaining Institutional Review Board (IRB) or Ethics Committee approval at each site;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical sites deviating from the clinical trial's protocol or dropping out of a clinical trial;
- the impacts of the COVID-19 pandemic or the conflict between Russia and Ukraine on our ongoing and planned preclinical studies and clinical trials;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in our preclinical studies and clinical trials, including product candidates manufactured in accordance with our specifications.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting, or completing our ongoing and planned clinical trials. We could encounter delays if a clinical trial is modified, suspended or terminated by us, by the IRBs or Ethics Committees of the institutions in which such clinical trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose a modification, suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or clinical trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed and our ability to generate product revenue from any of these product candidates will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Further, if patients drop out of our clinical trials, miss scheduled doses or follow-up visits, or otherwise fail to follow clinical trial protocols, whether as a result of the COVID-19 pandemic, actions taken to slow the spread of COVID-19 or otherwise, the integrity of data from our clinical trials may be compromised or not accepted by the FDA or comparable foreign regulatory authorities, which would represent a significant setback for the applicable program.

For the foregoing reasons, our ongoing and planned preclinical studies and clinical trials may not be successful. Any safety concerns observed in any one of our clinical trials in our targeted or contemplated indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have an adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

- the FDA or comparable foreign regulatory authorities disagreeing with the design or implementation of our clinical trials;
- obtaining regulatory authorizations to commence a trial, or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with contract research organizations (CROs) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional volunteers or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of a product candidate or obtaining sufficient quantities of other therapies or active pharmaceutical ingredients (APIs) for use in clinical trials;
- volunteers failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- volunteers choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- volunteers experiencing severe or unexpected drug-related or device-related adverse effects;
- occurrence of serious adverse events in clinical trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process or product formulation that may be necessary or desired;
- shortages in, or delays in obtaining, raw materials for manufacturing our product candidates or adequately scaling our manufacturing processes and procedures to deliver sufficient quantities for use in our clinical trials;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical protocol or relevant regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or comparable foreign regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or

adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

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

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

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

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

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

As an organization, we have conducted limited early clinical development, have not submitted an IND to the FDA and we have never conducted later-stage clinical trials or submitted a BLA or NDA, and may be unable to do so for any of our product candidates.

We are early in our development efforts for our product candidates, and we will need to successfully complete later-stage and pivotal clinical trials in order to obtain FDA or comparable foreign regulatory approval to market our current or any future product candidates. Carrying out later-stage clinical trials and the submission of a successful BLA or NDA is a complicated process. As an organization, we have conducted two Phase 1 clinical trials, both of which were conducted in Australia, and have not yet conducted any clinical trials for our other product candidates. We have not previously conducted any later stage or pivotal clinical trials, have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted a BLA, NDA or other comparable foreign regulatory submission for any product candidate. We also plan to conduct a number of clinical trials for multiple product candidates in parallel over the next several years. This may be a difficult process to manage with our limited resources and may divert the attention of management. In addition, we have had limited interactions with the FDA, and we have never filed an IND. We cannot be certain how many clinical trials of our product candidates will be required or how such trials will have to be designed. For example, we anticipate relying on data developed on the RaniPill platform to enable shortened or more efficient development for our subsequent product candidates, but this may not be the case and the FDA or other regulatory authorities may require us to perform a full suite of studies for each of our product candidates. Consequently, we may be unable to successfully and efficiently commence, execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and

may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting BLAs or NDAs for and commercializing our product candidates.

Because we have multiple product candidates in our clinical pipeline and are considering a variety of target indications, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific product candidates, indications and development programs. We also plan to conduct several clinical trials for our product candidates in parallel over the next several years, which may make our decision as to which product candidates to focus on more difficult. As a result, we may forgo or delay pursuit of opportunities with other product candidates or other indications that could have had greater commercial potential or likelihood of success. In addition, we are focused on developing the RaniPill capsule in addition to the drug formulations for use in the RaniPill capsule. While we intend to focus on well-characterized molecules with attractive commercial characteristics, focusing both on drug delivery and formulation will require substantial resource and attention. In addition, we are developing a new device with a payload capacity up to 20 mg, RaniPill HC, and in the future we may seek to develop other variations of the RaniPill capsule. In such cases, we need to redesign and conduct additional preclinical and clinical studies of any new design of the RaniPill capsule. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

Product candidates comprising a biologic or drug within the RaniPill capsule employ novel technologies that have not yet been approved by the FDA or comparable foreign regulatory authorities, and we anticipate that our applications will have to be submitted as original, standalone BLAs or NDAs. These regulatory authorities have limited experience in evaluating our technologies and product candidates. Our novel technologies also make it difficult to predict the time and cost of product candidate development.

We and our collaboration partners are developing product candidates based on novel technologies, and we intend to work closely with our collaboration partners to understand and deliver the requisite demonstration of safety and efficacy that the FDA and comparable foreign regulatory authorities may seek for the approval of our product candidates, which comprise a biologic or drug within the RaniPill capsule. It is possible that the regulatory approval process may take significant time and resources and require deliverables from independent third parties not under our control. For some of our product candidates, the regulatory approval path and requirements may not be clear or may change, which could add significant delay and expense. For example, although we have engaged in pre-submission meetings with the FDA, we have limited feedback from the FDA on the clinical trials that will be necessary to support BLA or NDA submissions for any of our product candidates. Delays or failure to obtain regulatory approval of any of the products that we or our collaboration partners develop using our novel technologies would adversely affect our business.

In addition, we are in the early stages of developing our platform and any development problems we experience in the future may cause significant delays or unanticipated costs, and such development problems may not be able to be overcome. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all. In addition, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our product candidates and understand these critical factors.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in the United States in March 2010, the ACA was enacted to increase access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and the health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the ACA of importance to our potential product candidates are the following:

- an annual, non-tax deductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents payable to the federal government based on each company's market share of prior year total sales of branded products to certain federal healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs in certain states;
- a Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, on June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Moreover, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period coverage through the Affordable Care Act marketplace, and instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to additional challenges in the future. It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA, or the impact any changes to the ACA may have on our ability to commercialize products or the prices we are able to obtain.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect through 2031 unless additional action is taken by Congress. However, the Medicare sequester reductions under the Budget Control Act of 2011 have been suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. Further, Congress is considering additional health reform measures. In addition, recently there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their commercial products. At the federal level, the former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as

well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within ninety (90) days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control drug pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates, if approved.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our product candidates or additional pricing pressures.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Risks Related to Our Business and Industry

We are heavily dependent on the success of our product candidates in our core programs, and if any of these product candidates fail to enter clinical trials, receive regulatory approval or are not successfully commercialized, our business would be adversely affected.

We currently have no product candidates that are in late-stage clinical trials or are approved for commercial sale, and we may never be able to develop a marketable product. We have a limited number of product candidates in early clinical development. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to the development of the RaniPill platform that is designed to enable the oral administration of a broad range of biologics and drugs used to treat multiple diseases and disorders. The RaniPill capsule may not receive regulatory approval in connection with any biologic or drug or, if approved, it may not be successfully commercialized. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of the RaniPill capsule for the indications we are seeking will remain subject to extensive regulation by the FDA and comparable foreign regulatory authorities in the United States and other countries, each of which has differing regulations. In addition, even if approved, pricing and reimbursement will be subject to further review and discussions with payors. We are not permitted to market any product candidate in the United States until after approval of a BLA or NDA from the FDA, or a similar marketing authorization from comparable authorities in any foreign countries until after approval of a marketing application by corresponding foreign regulatory authorities. We have conducted early clinical development of some of our product candidates. We will need to conduct larger, more extensive clinical trials in the target patient populations for these product candidates and their indications to support a potential application for regulatory approval by the FDA or corresponding foreign regulatory authorities.

We have not previously submitted a BLA or NDA to the FDA, or similar product approval filings to comparable foreign authorities, for any product candidate, and our product candidates may not be successful in clinical trials or receive regulatory approval. Filing an application and obtaining regulatory approval for a biologic product candidate or drug product candidate is an extensive, lengthy, expensive and inherently uncertain process, and the regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including:

- we may not be able to demonstrate that any of our product candidates is safe and effective to the satisfaction of the FDA or comparable foreign regulatory authorities;
- the FDA or comparable foreign regulatory authorities may require additional preclinical studies or clinical trials prior to granting approval, which would increase our costs and extend the pre-approval development process;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for approval;

- the FDA or comparable foreign regulatory authorities may disagree with the number, design, size, conduct or statistical analysis of one or more of our clinical trials;
- the FDA or comparable foreign regulatory authorities may disagree with, or not accept, our interpretation of data from our preclinical studies and clinical trials;
- the FDA or comparable foreign regulatory authorities may identify deficiencies in our manufacturing processes or facilities which would be required to be corrected prior to regulatory approval;
- the success or further approval of competitor products approved in indications in which we undertake development of our product candidates may change the standard of care or change the standard for approval of our product candidate in our proposed indications; and
- the FDA or comparable foreign regulatory authorities may change their approval policies or adopt new regulations.

Our product candidates will require additional research, clinical development, manufacturing activities, regulatory approval in multiple jurisdictions (if regulatory approval can be obtained at all), securing sources of commercial manufacturing supply and building of or partnering with a commercial organization. Our planned clinical trials for the RaniPill platform may not be initiated or completed in a timely manner or successfully, or at all. Further we may not advance any other product candidates into clinical trials. Moreover, any delay or setback in the development of any product candidate would be expected to adversely affect our business and cause our stock price to fall.

Risks Related to Our Intellectual Property

Our European patents are presently being challenged in Europe

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

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

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

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

The fourth opposition proceeding involves European Patent No. 3653223, which is generally directed to a swallowable device. We filed an initial response to the EPO.

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

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

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant as currently in effect (incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 26, 2021).
3.2	Amended and Restated Bylaws of the Registrant as currently in effect (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 9, 2021).
10.1+	Loan and Security Agreement, dated August 8, 2022, by and among the Registrant, its subsidiaries Rani Therapeutics, LLC and Rani Management Services, Inc., and Avenue Venture Opportunities Fund, L.P. (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 10, 2022).
10.2	Supplement to the Loan and Security Agreement, dated August 8, 2022, by and among the Registrant, its subsidiaries Rani Therapeutics, LLC and Rani Management Services, Inc., and Avenue Venture Opportunities Fund, L.P. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 10, 2022).
10.3	Form of Warrant to purchase share of Class A common stock of Registrant, issued to Avenue Venture Opportunities Fund, L.P. (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 10, 2022).
10.4	Controlled EquitySM Sales Agreement, dated August 24, 2022, by and among Rani Therapeutics Holdings, Inc., and Cantor Fitzgerald & Co. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 25, 2022).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*†	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

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

\+ Schedules and certain portions of the exhibits omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company agrees to furnish supplementally a copy of such schedules, or any section thereof, to the SEC upon request.

SIGNATURES

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

Rani Therapeutics Holdings, Inc.

Date: November 10, 2022

By: /s/ Talat Imran

Talat Imran
Chief Executive Officer
(Principal Executive Officer)

Date: November 10, 2022

By: /s/ Svai Sanford

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

Exhibit 31.1

CERTIFICATION

I, Talat Imran, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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

   (c) 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 10, 2022

/s/ Talat Imran
Talat Imran
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Svai Sanford, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) 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

   (c) 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 10, 2022

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

Exhibit 32.1

CERTIFICATION

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

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2022, 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 10, 2022

In Witness Whereof, the undersigned have set their hands hereto as of the 10th day of November, 2022.

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

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