UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2021

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 September 10, 2021, the registrant had 19,714,592 shares of Class A common stock, $0.0001 par value per share, outstanding, and 29,290,391 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 our consolidated subsidiary, Rani Therapeutics, LLC who do not hold shares of our Class B common stock can exchange their units for 1,545,811 shares of our Class A common stock.

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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 financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of clinical trials, research and development costs, manufacturing costs, regulatory approvals, 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 redesign and conduct additional preclinical and clinical studies of any future design of the RaniPill capsule to accommodate target payloads that are larger than the current capacity of the RaniPill capsule;
- 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 on our business;

- developments relating to our competitors and our industry, including competing product candidates and therapies; 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").

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations, and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties, and assumptions described in the section titled "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. 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 BALANCE SHEETS

	June 30, 2021 (Unaudited)	April 19, 2021
Assets:		
Cash	$ 10	$ 10
Total assets	$ 10	$ 10
Commitments and contingencies		
Stockholder's Equity:		
Common stock, $0.0001 par value per share, 1,000 shares authorized, issued and outstanding at June 30, 2021 and April 19, 2021	$ —	$ —
Additional paid-in-capital	10	10
Total stockholder's equity	$ 10	$ 10

The accompanying notes are an integral part of these condensed balance sheets.

RANI THERAPEUTICS HOLDINGS, INC.
NOTES TO THE UNAUDITED CONDENSED FINANCIAL STATEMENT

1. Organization

Rani Therapeutics Holdings, Inc. ("Rani Holdings" or "the Company") was formed as a Delaware corporation on April 6, 2021. Rani Holdings was formed for the purpose of completing a public offering and related transactions in order to carry on the business of Rani Therapeutics, LLC ("Rani LLC") and its subsidiary. As the manager of Rani LLC, Rani Holdings is expected to operate and control all of the business and affairs of Rani LLC, and through Rani LLC, continue to conduct the business now conducted by these subsidiaries.

In August 2021, the Company closed its initial public offering ("the Offering" or "IPO") and related organization transactions whereby the Company became a holding company, was admitted to Rani LLC as the sole managing member, and its principal asset became the common units of Rani LLC that it owns. As the sole managing member of Rani LLC, the Company operates and controls all of the business and affairs of Rani LLC, and through its subsidiary, conducts its business. As a result, the Company will consolidate the financial results of Rani LLC and will report a non-controlling interest representing the Rani LLC interests held by InCube Labs, LLC, a Delaware limited liability company and certain of its affiliates ("ICL") and certain current and former executive officers, employees and directors of Rani LLC.

2. Summary of Significant Accounting Policies

Basis of Presentation and Accounting

The accompanying unaudited condensed balance sheets have been prepared in accordance with accounting principles generally accepted in the United States of America ("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 GAAP for complete financial statements. Separate statements of operations, comprehensive income, changes in stockholder's equity, and cash flows have not been presented as of June 30, 2021 because there have been no activities except in connection with the Company's formation.

The condensed balance sheet presented as of April 19, 2021, has been derived from the audited balance sheet as of that date. The condensed balance sheets and notes are presented as permitted by Form 10-Q and do not contain all information that is included in the annual financial statements and notes thereto of the Company. Therefore, these interim condensed balance sheets and notes should be read in conjunction with the Company's audited balance sheet and notes included in the Company's Registration Statement on Form S-1 (No. 333-257809) filed with the SEC.

The financial statement has been prepared in accordance with GAAP.

The financial statement has been prepared assuming Rani Holdings will continue as a going concern, which contemplates, among other things, the realization of assets and satisfaction of liabilities in the normal course of business.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the balance sheet. Actual results could differ from those estimates.

Cash

Cash consists of a deposit in-transit.

3. Stockholder's Equity

On April 6, 2021, Rani Holdings was authorized to issue 1,000 shares of common stock, par value $0.0001 per share, all of which have been issued and are outstanding. On the balance sheet date, Rani Holdings issued 1,000 shares at a purchase price of $0.01 per share for aggregate gross proceeds of $10.00 to Rani LLC. As of the balance sheet date, Rani Holdings had outstanding 1,000 shares all of which were owned by Rani LLC.

In connection with the Company's Offering, the Company's board of directors approved an amended and restated certificate of incorporation (the "Amended and Restated Certificate of Incorporation"). The Amended and Restated Certificate of Incorporation authorizes the issuance of up to 800,000,000 shares of Class A common stock, up to 40,000,000 shares of Class B common stock, 20,000,000 shares of Class C common stock and 20,000,000 shares of preferred stock, each having a par value of $0.0001 per share. The Class B common stock has no rights to receive any distributions or dividends, whether cash or stock. Each share of Class A common stock entitles its holders to one vote per share and each share of Class B common stock entitles its holders to 10 votes per share on all matters presented to the Company's stockholders. Shares of Class C common stock have no voting rights, except as otherwise required by law.

4. Subsequent Events

Organization Transactions

In August 2021, and in connection with the completion of the Offering, the Company was party to the following organization transactions (the "Organization Transactions"):

- Appointed as Rani LLC's sole managing member through an amendment and restatement of the Rani LLC operating agreement (the "Rani LLC Agreement");
- 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 Rani Holdings' 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 ("Former LLC Owners") on a one-for-one basis;
- Issued 29,290,391 shares of Class B common stock to the certain individuals and entities that continued to hold interests in Rani LLC after the Offering ("the Containing LLC Owners") in exchange for an equal amount of Rani LLC Interests;
- Entered into a registration rights agreement with certain of the Continuing LLC Owners.

The Continuing LLC Owners of Rani LLC may, subject to the terms of the Rani LLC Agreement, exchange their interests in Rani LLC ("LLC Interests") for the Company's Class A common stock on a one-to-one basis with a corresponding number of such shares of Class B common stock; 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 LLC Interest redeemed. Any shares of Class B common stock will be cancelled on a one-for-one basis if the Company, at the election of the Continuing LLC Owners, redeem or exchange such LLC Interests 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 tax that Rani Holdings 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. Certain individuals who continue to own interests in Rani LLC but do not hold shares of our Class B common stock can exchange their units for 1,545,811 shares of our Class A common stock.

Initial Public Offering

In August 2021, the Company closed an initial public offering 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 $73.7 million in net proceeds, after deducting underwriting discounts, offering costs and commissions.

The Company used the proceeds from the Offering to purchase 7,666,667 newly issued Class A units of Rani LLC.

Tax Receivable Agreement

In August 2021, in connection with the Offering, Rani Holdings entered into a tax receivable agreement with certain of the Continuing LLC Owners that provides for the payment by Rani Holdings to such Continuing LLC Owners of 85% of the amount of tax benefits, if any, that the Company 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 membership interests of Rani LLC and (b) payments under the tax receivable agreement and (ii) certain other benefits arising from payments under the tax receivable agreement.

Equity Incentive Plans

In July 2021, the Company adopted and its stockholders approved, the Rani Therapeutics Holdings, Inc. 2021 Equity Incentive Plan (the “2021 Plan”). The 2021 Plan provides for the grant of incentive stock options ("ISOs"), non-statutory stock options ("NSOs"), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based awards and other awards for shares of the Company’s Class A common stock.

In July 2021, the Company's board of directors adopted and its stockholders approved, the Rani Therapeutics Holdings, Inc. 2021 Employee Stock Purchase Plan (the “ESPP”).

The Company reserved 500,000 shares of Class A Common Stock for issuance under the ESPP and 5,500,000 shares of Class A common stock for future issuance under the 2021 Plan.

RANI THERAPEUTICS, LLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except unit amounts)

	June 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 69,314	$ 73,058
Related party note receivable	—	1,720
Prepaid expenses	165	167
Total current assets	69,479	74,945
Deferred financing costs	3,412	—
Property and equipment, net	4,430	4,470
Total assets	$ 77,321	$ 79,415
Liabilities, Convertible Preferred Units and Members' Deficit		
Current liabilities:		
Accounts payable	$ 1,667	$ 537
Related party payable	883	145
Accrued expenses	2,921	550
Deferred revenue	—	2,717
Current portion of long-term debt	3,884	1,359
Total current liabilities	9,355	5,308
Preferred unit warrant liability	606	320
Long-term debt, less current portion	—	2,412
Total liabilities	9,961	8,040
Commitments and contingencies (Note 10)		
Convertible preferred units, 32,620,000 units authorized, and 27,629,804 and 26,745,528 units issued and outstanding at June 30, 2021 and December 31, 2020, respectively	191,034	184,714
Members' deficit:		
Common units, 101,000,000 units authorized, and 46,896,280 and 46,890,280 units issued and outstanding at June 30, 2021 and December 31, 2020, respectively	1,412	664
Accumulated deficit	(125,086)	(114,003)
Total members' deficit	(123,674)	(113,339)
Total liabilities, convertible preferred units and members' deficit	$ 77,321	$ 79,415

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

RANI THERAPEUTICS, LLC
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except unit and per unit amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Contract revenue	$ 1,961	$ 60	$ 2,717	$ 143
Operating expenses				
Research and development	3,759	2,558	7,106	6,618
General and administrative	3,460	892	6,067	2,299
Total operating expenses	$ 7,219	$ 3,450	$ 13,173	$ 8,917
Loss from operations	(5,258)	(3,390)	(10,456)	(8,774)
Other income (expense), net				
Interest income	13	12	60	74
Interest expense and other, net	(169)	(2)	(357)	(2)
Change in estimated fair value of preferred unit warrant	(70)	672	(286)	655
Loss before income taxes	(5,484)	(2,708)	(11,039)	(8,047)
Income tax expense	(1)	(6)	(44)	(17)
Net loss and comprehensive loss	$ (5,485)	$ (2,714)	$ (11,083)	$ (8,064)
Net loss per unit, basic and diluted	$ (0.12)	$ (0.06)	$ (0.24)	$ (0.17)
Weighted-average common units outstanding—basic and diluted	46,896,280	46,890,280	46,896,081	46,890,280

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

RANI THERAPEUTICS, LLC
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN CONVERTIBLE PREFERRED UNITS AND MEMBERS' DEFICIT
(in thousands, except unit amounts)
(Unaudited)

For the Six Months Ended June 30, 2020 (unaudited)	Convertible Preferred Units	Convertible Preferred Amount	Common Units	Common Amount	Accumulated Deficit	Total Members' Deficit
Balance at December 31, 2019	17,084,696	$ 115,505	46,890,280	$ 664	$ (97,300)	$ (96,636)
Net loss	—	—	—	—	(5,350)	(5,350)
Balance at March 31, 2020	17,084,696	$ 115,505	46,890,280	$ 664	$ (102,650)	$ (101,986)
Net loss	—	—	—	—	(2,714)	(2,714)
Balance at June 30, 2020	17,084,696	$ 115,505	46,890,280	$ 664	$ (105,364)	$ (104,700)

For the Six Months Ended June 30, 2021 (unaudited)	Convertible Preferred Units	Convertible Preferred Amount	Common Units	Common Amount	Accumulated Deficit	Total Members' Deficit
Balance at December 31, 2020	26,745,528	$ 184,714	46,890,280	$ 664	$ (114,003)	$ (113,339)
Issuance of Series E preferred units	884,276	6,320	—	—	—	—
Exercise of warrant for common units	—	—	6,000	13	—	13
Equity-based compensation from secondary sales transactions	—	—	—	453	—	453
Net loss	—	—	—	—	(5,598)	(5,598)
Balance at March 31, 2021	27,629,804	$ 191,034	46,896,280	$ 1,130	$ (119,601)	$ (118,471)
Equity-based compensation	—	—	—	282	—	282
Net loss	—	—	—	—	(5,485)	(5,485)
Balance at June 30, 2021	27,629,804	$ 191,034	46,896,280	$ 1,412	$ (125,086)	$ (123,674)

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

RANI THERAPEUTICS, LLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities		
Net loss	$ (11,083)	$ (8,064)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	264	303
Equity-based compensation expense	735	—
Change in fair value of preferred unit warrant liability	286	(655)
Other	124	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	2	(79)
Accounts receivable	—	(3,000)
Related party receivable	—	(15)
Accounts payable	421	1,662
Accrued expenses	1,554	(310)
Related party payable	738	(1,629)
Deferred revenue	(2,717)	2,857
Net cash used in operating activities	(9,676)	(8,930)
Cash flows from investing activities		
Purchases of property and equipment	(235)	(944)
Net cash used in investing activities	(235)	(944)
Cash flows from financing activities		
Proceeds from issuance of preferred units, net of issuance costs	6,320	—
Proceeds from exercise of warrants for common units	13	—
Proceeds from the Paycheck Protection Program Loan	—	1,254
Payment of deferred financing costs	(1,885)	—
Principal and interest repayments from related party for note receivable	1,720	—
Net cash provided by financing activities	6,167	1,254
Net decrease in cash and cash equivalents	(3,744)	(8,620)
Cash and cash equivalents, beginning of period	73,058	16,536
Cash and cash equivalents, end of period	$ 69,314	$ 7,916
Supplemental disclosures of cash flow information		
Cash paid for interest	$ 170	$ —
Supplemental disclosures of non-cash investing and financing activities		
Property and equipment purchases included in accounts payable and accrued expenses	$ —	$ 185
Deferred financing costs included in accounts payable and accrued expenses	$ 1,527	$ —

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, LLC ("Rani" or the "Company") is a clinical stage biotherapeutics company advancing technologies to enable the development of orally administered biologics. The Company has developed the RaniPill capsule, which is a novel, proprietary and patented platform technology, intended to replace subcutaneous or intravenous injection of biologics with oral dosing. The Company was organized under the laws of the State of California in February 2012, as a limited liability company. The Company is managed by a board of managers ("Board of Managers") as prescribed by its operating agreement. The Company formed a wholly-owned subsidiary, Rani Management Services, Inc. ("RMS") in November 2019. The Company is headquartered in San Jose, California and operates in one segment.

Up to December 31, 2019, Rani maintained no employees of its own and contracted with InCube Labs, LLC ("ICL"), the majority common unit holder of the Company and a related party, to provide research, development and administrative services. ICL and Rani have common management and interest holders and, in the course of performing under the terms of the service agreements, ICL employees acted on behalf of Rani. Effective January 1, 2020, the ICL personnel that were substantially dedicated to providing services to Rani were hired by RMS as full-time employees (see Note 6).

Rani Therapeutics Holdings, Inc. ("Rani Holdings") was incorporated in April 2021 for the purpose of facilitating an initial public offering in order to carry on the Company's business. In August 2021, Rani Holdings closed its initial public offering (the "Offering" or "IPO") of 7,666,667 million shares of 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 $73.7 million in net proceeds, after deducting underwriting discounts, offering costs and commissions.

In connection with the Offering, Rani Holdings became a holding company and its principal asset is the Class A common units of Rani that it owns. As the sole managing member of the Company, Rani Holdings operates and controls all of the Company's operations, and through Rani and its subsidiary, conducts all of Rani's business.

Liquidity

The Company has incurred recurring losses since its inception, including net losses of $11.1 million for the six months ended June 30, 2021. As of June 30, 2021, the Company had an accumulated deficit of $125.1 million and for the six months ended June 30, 2021 had negative cash flows from operations of $9.7 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 and cash equivalents of $69.3 million as of June 30, 2021 and net proceeds of $73.7 million from the Offering will be sufficient to fund its operations through at least one year 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, 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 demand for 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.

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 condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

Unaudited Interim Financial Information

The accompanying condensed consolidated balance sheet at June 30, 2021, condensed consolidated statements of operations and comprehensive loss and condensed consolidated statements of changes in convertible preferred units and members' deficit for the three-month and six-month periods ended June 30, 2021 and 2020 and the condensed consolidated statements of cash flows for the six-month periods ended June 30, 2021 and 2020 are unaudited. In management's opinion, the unaudited condensed consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements, and include all adjustments necessary to state fairly the financial position as of June 30, 2021, the results of its operations for the three and six months ended June 30, 2021 and 2020 and the condensed consolidated statement of changes in convertible preferred units and members' deficit for the three months and six months ended June 30, 2021 and 2020. The consolidated balance sheet as of December 31, 2020 included herein was derived from the audited consolidated financial statements as of that date. The results for the three months and six months ended June 30, 2021 are not necessarily indicative of the operating results to be expected for the full fiscal year or any future period. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted. Therefore, these interim condensed financial statements should be read in conjunction with the Company's audited consolidated financial statements included in Rani Holdings' Registration Statement on Form S-1 (No. 333-257809) filed with the SEC.

Use of Estimates

The preparation of the 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 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. Significant estimates include, but are not limited to, recovery of long-lived assets, unvested equity-based compensation expense, research and development accruals, the fair value of Profits Interests, and the fair value of the Company's preferred unit warrants. Actual results may differ materially and adversely from these estimates.

Revenue Recognition

The Company enters into evaluation arrangements with certain pharmaceutical partners, under which the Company performs evaluation services of the partner's drug molecules using the RaniPill capsule.

Revenue is recognized when control of promised goods or services is transferred to a customer in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for its arrangements with customers, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Revenue for an individual contract is recognized at the related transaction price, which is the amount the Company expects to be entitled to in exchange for transferring these services. The terms of the evaluation services agreements usually include payments for evaluation services and evaluation milestones based on a decision to extend the agreement. The transaction price of the evaluation services contracts may include variable consideration. Application of the constraint for variable consideration requires judgment. The constraint for variable consideration is applied such that it is probable a significant reversal of revenue will not occur when the uncertainty associated with the contingency is resolved. Application of the constraint for variable consideration is updated at each reporting period as a revision to the estimated transaction price. For arrangements where the anticipated period between timing of transfer of services and the timing of payment is one year or less, the Company has elected to not assess whether a significant financing component exists. The Company recognizes evaluation services revenue over the period in which evaluation services are provided. Specifically, the Company recognizes revenue using an output method to measure progress, using samples processed relative to total expected samples to be processed as its measure of progress. For services under these arrangements, costs incurred are included in research and development expenses in the Company's consolidated statements of operations and comprehensive loss.

Customer options, such as options granted to allow a customer to acquire later stage evaluation services, are evaluated at contract inception in order to determine whether those options provide a material right (i.e., an optional good or service offered for free or at a discount) to the customer. If the customer options represent a material right, the material right is treated as a separate performance obligation at the outset of the arrangement. The Company allocates the transaction price to material rights based on the standalone selling price, and revenue is recognized when or as the future goods or services are transferred or when the option expires. Customer options that are not material rights do not give rise to a separate performance obligation, and as such, the additional consideration that would result from a customer exercising an option in the future is not included in the transaction price for the current contract. Instead, the option is deemed a marketing offer, and additional option fee payments are recognized or being

recognized as revenue when the licensee exercises the option. The exercise of an option that does not represent a material right is treated as a separate contract for accounting purposes.

Revenue is recognized for each distinct performance obligation as control is transferred to the customer. The Company recognizes revenue from its evaluation services over time as services are delivered, using a cost-based input method of revenue recognition over the contract term. The cost-based input measured is based on an estimate of total costs to be incurred to deliver the services over the contract period compared to costs incurred to date for each contract. The Company's evaluation of estimated costs to perform the services typically includes estimates for effort related to contracted research, formulation, and animal testing. These estimates are based on the Company's reasonable assumptions and its historical experience. Actual results may differ materially and adversely from these estimates.

Incremental costs of obtaining contracts are expensed when incurred when the amortization period of the assets that otherwise would have been recognized is one year or less. To date none of these costs have been material. The costs to fulfill the contracts are determined to be immaterial and are recognized as an expense when incurred.

Contract assets are generated when contractual billing schedules differ from revenue recognition timing and the Company records a contract receivable when it has an unconditional right to consideration. No contract assets balance was recorded as of June 30, 2021 and December 31, 2020.

Contract liabilities are recorded as deferred revenue when cash payments are received or due in advance of performance or where the Company has unsatisfied performance obligations. As of December 31, 2020 the Company had deferred revenue of $2.7 million. There was no deferred revenue as of June 30, 2021.

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 December 2019, a novel strain of coronavirus, which causes the disease known as COVID-19, was reported to have surfaced in Wuhan, China. Since then, COVID-19 coronavirus has spread globally. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The COVID-19 pandemic has impacted and may continue to impact the Company's third-party manufacturers and suppliers, which could disrupt its supply chain or the availability or cost of materials. The effects of the public health directives and the Company's work-from-home policies may negatively impact productivity, disrupt its business, and delay clinical programs and timelines and future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on the Company's ability to conduct business in the ordinary course. These and similar, and perhaps more severe, disruptions in the Company's operations could negatively impact business, results of operations and financial condition, including its ability to obtain financing. To date, the Company has not incurred impairment losses in the carrying values of its assets as a result of the pandemic and is not aware of any specific related event or circumstances that would require the Company to revise its estimates reflected in these condensed consolidated financial statements.

The Company cannot be certain what the overall impact of the COVID-19 pandemic will be on its business and prospects. The extent to which the COVID-19 pandemic will further directly or indirectly impact its business, results of operations, financial condition, and liquidity, including planned and future clinical trials and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19, the actions taken to contain or treat it, and the duration and intensity of the related effects. In addition, the Company could see some limitations on employee resources that would otherwise be focused on its operation, including but not limited to sickness of employees or their families, the desire of employees to avoid contact with large groups of people, and increased reliance on working from home. If the financial markets and/or the overall economy are impacted for an extended period, the Company's business, financial condition, results of operations and prospects may be adversely affected.

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 equivalents, prepaid expenses, accounts payable, and accruals approximate their fair value due to their short-term nature. The fair value of the Company's long-term debt approximates its carrying value based on borrowing rates currently available to the Company for debt with similar terms and maturities (Level 2 inputs).

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

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist primarily of contract research fees and process development, outsourced labor and related expenses for personnel, facilities cost, fees paid to consultants and advisors, depreciation and supplies used in research and development and costs incurred under our evaluation agreements. Payments made prior to the receipt of goods or services to be used in research and development activities are recorded as prepaid expenses until the related goods or services are received. Until future commercialization is considered probable and the future economic benefit is expected to be realized the Company does not capitalize pre-launch inventory costs. Costs of property and equipment related to scaling-up of the 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.

Clinical and preclinical costs are a component of research and development expense. The Company accrues and expenses clinical and pre-clinical trial activities performed by third parties based upon actual work completed in accordance with agreements established with its service providers. The Company determines the actual costs through discussions with internal personnel and external service providers as to the progress or stage of completion of services and the agreed-upon fee to be paid for such services.

Equity-Based Compensation

The Company has granted equity-based awards to employees of ICL performing services for the Company, employees of and Board Managers of the Company and consultants in the form of non-vested incentive units ("Profits Interests") and/or options to purchase common units. All awards of Profits Interests and options to purchase common units are measured based on the estimated fair value of the award on the date of grant. Forfeitures are recognized when they occur. All of the Profits Interests are subject to service and performance-based conditions and the Company evaluates the probability of achieving each performance-based condition at each reporting date and begins to recognize distribution of equity for ICL employee awards and equity-based compensation expense for Company and consultant awards when it is deemed probable that the performance-based condition will be met using the accelerated attribution method over the requisite service period. The options to purchase common units are subject to service conditions and generally vest over three or four years.

The Company utilizes estimates and assumptions in determining the fair value of its Profits Interests and options to purchase common units on the date of grant. As the Company was not a publicly traded company in the six months ended June 30, 2021 and 2020, the Company utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its preferred units, common units and Profits Interests. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include several objective and subjective factors, including probability weighting of events, volatility, time to an exit event, a risk-free interest rate, the prices at which the Company sold preferred units, the superior rights, and preferences of the preferred units senior to the Company's common units at the time, and a discount for the lack of marketability. Changes to the key assumptions used in the valuations could result in different fair values at each valuation date.

The Company determines the grant-date fair value of options to purchase common units using the Black-Scholes option-pricing model which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the unit option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield. The grant-date fair value of awards is amortized over the employees' requisite service period on a straight-line basis, or the consultants' vesting period as the services are rendered. Equity-based compensation is classified in the accompanying condensed consolidated statements of operations and comprehensive loss based on the function to which the related services are provided.

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. The Company did not have any other comprehensive loss for any of the periods presented, and therefore comprehensive loss was the same as the Company's net loss.

Net Loss Per Unit

Basic net loss per unit is computed using the weighted-average number of common units outstanding for the period, without consideration of potential dilutive securities. Diluted net loss per unit is computed using the weighted-average number of common units outstanding during the period and, if dilutive, the weighted-average number of potential common units. Net loss per unit attributable to common unitholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per unit for the holders of the Company's common units and participating securities.

The preferred unit warrants and convertible note are non-participating securities, while the Profits Interests participate in the gains and losses of the Company once the participation threshold is reached. The Company's convertible preferred units contain participation rights in any dividend paid by the Company and are deemed to be participating securities. The convertible preferred units do not include a contractual obligation to participate in losses of the Company and are not included in the calculation of net loss per unit in the periods in which a net loss is recorded. The Company's convertible preferred units, common unit warrants, preferred unit warrants, convertible notes and Profits Interests are considered potentially dilutive.

The Company makes adjustments to diluted net loss to reflect the reversal of gains on the change in the value of preferred unit warrant liabilities, assuming conversion of warrants to acquire convertible preferred units at the beginning of the period or at time of issuance, if later, to the extent that those preferred unit warrants are dilutive. The Company computes diluted net loss per unit after giving consideration to all potentially dilutive common units outstanding during the period, determined using the treasury stock and if-converted methods, as applicable, except where the effect of including such securities would be antidilutive.

For the six months ended June 30, 2021 and 2020, the Company reported a net loss. The potentially dilutive common units were anti-dilutive, except for the series B preferred unit warrants, which were considered dilutive but did not affect the net loss per share. As a result, basic and diluted net loss per unit were the same.

Deferred financing costs

Deferred financing costs, which consist of direct incremental legal, consulting, banking and accounting fees primarily relating to the Company's Offering, are capitalized and will be offset against proceeds upon the consummation of the offering within members' deficit. As of December 31, 2020, there were no capitalized deferred financing costs on the condensed consolidated balance sheet. As of June 30, 2021, there were $3.4 million of deferred financing costs recorded as a long-term asset on the condensed consolidated balance sheet.

New Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (the "FASB") issued ASU 2016-02, *Leases* ("Topic 842"), as subsequently amended, to improve financial reporting and disclosures about leasing transactions. Topic 842 requires companies that lease assets to recognize on the condensed consolidated balance sheet the assets and liabilities for the rights and obligations created by those leases, where the lease terms exceed 12 months. The recognition, measurement, and presentation of expense and cash flows arising from a lease by a lessee will depend primarily on its classification as a finance or operating lease; both types of leases will be recognized on the condensed consolidated balance sheet. Topic 842 also requires disclosures to help financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. On June 3, 2020, the FASB amended the effective dates of Topic 842 to give immediate relief from business disruptions caused by the COVID-19 pandemic and provided a one-year deferral of the effective date for nonpublic companies. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, and assuming the Company continues to be considered an emerging growth company, Topic 842 will be effective for the Company on January 1, 2022. The

Company has not yet determined the effects of Topic 842 on its condensed consolidated financial statements but does expect the adoption of Topic 842 will have a material impact on the Company's consolidated financial statements and related notes to the recognition of right of use ("ROU") assets and lease liabilities on the Company's consolidated balance sheets, but it will not have a material impact on the Company's consolidated statement of income. The adoption of Topic 842 will also result in enhanced disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses* ("ASU 2016-13") to require the measurement of expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, and assuming the Company continues to be considered an emerging growth company, ASU 2016-13 will be effective for the Company on January 1, 2023. The Company has not yet determined the potential effects of ASU 2016-13 on its condensed consolidated financial statements and disclosures.

3. Fair Value Measurements

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

	As of June 30, 2021		
	Level 1	Level 2	Level 3
Assets:			
Money market funds	$ 67,002	$ —	$ —
Total assets	$ 67,002	$ —	$ —
Liabilities:			
Preferred unit warrant liability	$ —	$ —	$ 606
Total liabilities	$ —	$ —	$ 606

	As of December 31, 2020		
	Level 1	Level 2	Level 3
Assets:			
Money market funds	$ 71,666	$ —	$ —
Total assets	$ 71,666	$ —	$ —
Liabilities:			
Preferred unit warrant liability	$ —	$ —	$ 320
Total liabilities	$ —	$ —	$ 320

The Company estimates the fair value of its money market funds by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value.

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

The Company holds a Level 3 liability associated with preferred unit warrants that were issued in connection with the Company's convertible note and preferred unit financings. The preferred unit warrants are accounted for as liabilities.

The following table summarizes the significant unobservable inputs used in the fair value measurement of the Series E preferred unit warrant liability as of June 30, 2021:

Fair Value (in thousands)	Valuation Technique	Unobservable Input	Range	Weighted Average
$606	Hybrid between the probability weighted expected return and option pricing methods	Time to exit	0.1 - 2.3 years	0.3 years
		Probability of exit events	10% - 90%	80%
		Discount for lack of marketability	10% - 31%	12%
		Volatility	72%	72%

Significant increases or decreases in time to exit, probability of exit, discount for lack of marketability and volatility would have resulted in a significantly lower or higher fair value measurement as of June 30, 2021.

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Balance at beginning of period	$ 536	$ 672	$ 320	$ 655
Change in estimated fair value of Series B warrants	—	(1)	—	16
Change in estimated fair value of Series E warrants	70	—	286	—
Expiration of Series B warrants	—	(671)	—	(671)
Balance at end of period	**$ 606**	**$ —**	**$ 606**	**$ —**

4. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	June 30, 2021	December 31, 2020
Accrued professional fees	$ 348	$ —
Payroll and related	1,222	136
Deferred financing costs	998	—
Other	353	414
Total accrued expenses	**$ 2,921**	**$ 550**

5. Evaluation Agreements

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 be a single performance obligation.

For revenue recognition purposes, the Company determined that the duration of the contract began on the effective date in November 2017 and ends upon completion of the Research and Development Services. The contract duration is defined as the period in which parties to the contract have present enforceable rights and obligations. The Company also analyzed the impact of Takeda terminating the agreement prior to the completion of the performance obligation and determined, considering both quantitative and qualitative factors, that there were substantive non-monetary penalties to Takeda for doing so.

The Company has determined that the cost-based input method most faithfully depicts the transfer of its performance obligation to Takeda. Accordingly, the Company recognizes its contract revenue based on actual costs incurred as a percentage of total estimated costs the Company expects to incur to deliver its performance obligation. These actual costs consist of internal labor efforts, in vivo testing services and materials costs related to the Takeda agreement, as the costs incurred over time reflect the transfer of its performance obligations to Takeda. The cumulative effect of revisions to estimated costs to complete the Company's performance obligation will be recorded in the period in which changes are identified and amounts can be reasonably estimated. A significant change in these assumptions and estimates could have a material impact on the timing and amount of revenue recognized in future periods.

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 the three months ended June 30, 2021.

For the three months ended June 30, 2021 and 2020, the Company recognized contract revenue related to the Takeda agreement of $2.0 million and $0.1 million, respectively.

For the six months ended June 30, 2021 and 2020, the Company recognized contract revenue related to the Takeda agreement of $2.7 million and $0.1 million, respectively. As of December 31, 2020, deferred revenue related to the remaining identified performance obligation for the Takeda agreement of $2.7 million was recorded on the condensed consolidated balance sheets. There was no deferred revenue as of June 30, 2021.

Changes in the deferred revenue balance are as follows (in thousands):

	June 30, 2021	December 31, 2020
Balance at beginning of period	$ 2,717	$ 179
Additions	—	3,000
Deductions	(2,717)	(462)
Balance at end of period	**$ —**	**$ 2,717**

There were no receivables or net contract assets recorded as of June 30, 2021 or December 31, 2020 associated with the Takeda agreement. The Company expensed all incremental costs of obtaining the Takeda agreements, as such amounts were insignificant.

6. Related Party Transactions

ICL is wholly-owned by the Company’s founder and Executive Chairman and his family. The Company’s Chief Scientific Officer is the brother of the founder and Executive Chairman and uncle of the Company’s Chief Executive Officer. The founder and Executive Chairman is also the father of the Company’s Chief Executive Officer.

Services agreements

In January 2019, the Company entered into a one year service agreement with ICL. This agreement was amended in January 2020 to extend the period for an additional year and expired in December 2020. The Company is presently operating under a service agreement with ICL executed in June 2021, retroactive to January 1, 2021. The Company or ICL may terminate services under the service agreement upon 60 days' notice to the other party, except for occupancy which requires six months' notice. The service agreement specifies the scope of services to be provided by ICL as well as the methods for determining the costs of services for the year ended December 31, 2021. Costs are billed on a monthly basis and based upon the hours incurred by ICL employees working on behalf of Rani as well as allocations of expenses based upon Rani’s utilization of ICL’s facilities and equipment.

In June 2021, RMS entered into the RMS-ICL Service Agreement with ICL effective January 1, 2021 (the "RMS-ICL Service Agreement"), pursuant to which ICL agreed to rent a specified portion of its facility to RMS. Additionally, RMS and ICL agreed to provide personnel services to the other upon requests based on rates specified in the agreement. The RMS-ICL Service Agreement has a 12-month term and will automatically renew for successive 12-month periods unless terminated. For the six months ended June 30, 2020 and 2021, RMS charged ICL $0.2 million and $0.3 million for services performed, respectively, and such amounts charged were recorded as a reduction to research and development expense in the condensed consolidated statement of operations and comprehensive loss.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 123	$ (63)	$ 156	$ 121
General and administrative	184	207	366	451
Total	**$ 307**	**$ 144**	**$ 522**	**$ 572**

The Company's eligible employees are permitted to participate in ICL's 401(k) Plan ("401(k) Plan"). Participation in the 401(k) Plan is offered for the benefit of the employees, including the Company's named executive officers, and who satisfy certain eligibility requirements.

All of Rani's facilities are owned by an entity affiliated with the Company's Executive Chairman. Rani pays for the use of these facilities through the services agreement with ICL.

Financing activity

From inception to the first half of 2017, Rani 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 June 2017, Rani converted the outstanding net advances of $6.6 million to ICL into three notes receivable. The notes provide for interest at 1.97% compounded annually, loan fees of 2.75% and are payable upon demand to Rani any time after January 1, 2024. During 2020, the Company received $0.2 million in payments for interest and repayment of principal on the remaining notes receivable.

As of December 31, 2020, $1.7 million of the notes receivable was outstanding. In March 2021, the outstanding balance due, including all accrued interest, was fully repaid by ICL.

During 2020, the Company amended certain Series B warrants held by an entity affiliated with ICL. In December 2020, this entity elected to cashless exercise all of their Series B warrants in return for 51,341 Series B units (see Note 7). This same entity also acquired 59,312 Series D units for $1.0 million in 2017.

Exclusive License, Intellectual Property and Common Unit Purchase Agreement

The Company 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 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 License Agreement, the Company will 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. The Company will cover patent-related expenses and, after a certain period, the Company will have the right to acquire four specified U.S. patent families from ICL by making a one-time payment of $250,000 to ICL for each U.S. 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 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 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.

Board Services

During the year ended December 31, 2020, the Company made a $0.2 million payment to a member of the Board of Managers for legacy board services provided to the Company.

Secondary Sales Transactions

In February 2021, one of the Company's named executive officer's and then member of the Board of Managers, and a current member of the Board of Managers 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.

7. Warrants

Preferred unit warrants

In September 2020, in conjunction with a loan and security Agreement (see Note 11), the Company issued warrants to purchase up to 118,929 Series E preferred units. The Series E warrants are exercisable for a period of seven years from the grant date at an exercise price of $7.1471 per unit. At June 30, 2021 and December 31, 2020 all of these Series E warrants were outstanding. In the event of a change of control or IPO, the Series E warrants were to automatically be exchanged for the same number of units of the Company's securities for no consideration had the holder of the warrant elected to exercise the warrant immediately prior to a change in control or IPO. In conjunction with the Rani Holdings IPO in August 2021, the Series A warrants were exchanged for Class A common units of the Company as part of a set of organization transactions. These Class A common units were then exchanged for 62,887 shares of Rani Holdings Class A common stock.

Common unit warrants

In 2017, in conjunction with the Series D convertible preferred unit financing, the Company issued 229,315 common unit warrants with an exercise price of $2.18 per unit and an exercise period of five years. The Company recorded the issuance-date fair value of the common warrants of $0.3 million in equity as the warrant met all criteria for equity classification. In January 2021, 6,000 common unit warrants were exercised at $2.18 per share. At June 30, 2021 and December 31, 2020, 223,315 common unit warrants and 229,315 common unit warrants were outstanding, respectively. In conjunction with the Rani Holdings IPO in August 2021, the common warrants were net exchanged for Class A common units of the Company as part of a set of organization transactions. These Class A common units were then exchanged for 71,867 shares of Rani Holdings Class A common stock.

8. Members' deficit

Under the Fourth Amended and Restated Limited Liability Company Agreement (the "Operating Agreement"), the Company is authorized to issue 101,000,000 common units, of which 10,850,000 have been reserved for issuance as Profits Interests and 32,620,000 are 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 Company who hold these common and Preferred Units are 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 are not obligated to make capital contributions to the Company. The Company will dissolve generally only upon the written consent of a majority of the members.

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

Convertible Preferred Units

In October 2020, the Company entered into a Series E Preferred Unit Purchase Agreement (“Series E Agreement”). Between October 2020 and January 2021, the Company sold a total of 10,493,767 units of its Series E units at a purchase price of $7.1471 per unit, for total net proceeds of $74.8 million, net of issuance costs of $0.2 million. The subsequent closings were considered to be mutual options as neither the purchasers nor the Company had a commitment or obligation to purchase or sell additional units. As such, these rights were not accounted for separately. The Series E units were sold at a price lower than the Series C-1 and Series D units resulting in an anti-dilution adjustment to the Series C-1 and Series D conversion prices. The anti-dilution adjustment did not create a contingent beneficial conversion.

The Company’s convertible preferred units consisted of the following (in thousands, except unit amounts):

	Units		Carrying	Liquidation	Units issuable
June 30, 2021	**Authorized**	**Outstanding**	**Value**	**Preference**	**upon conversion**
Series A convertible preferred units	4,000,000	4,000,000	3,974	8,000	4,000,000
Series B convertible preferred units	2,600,000	2,510,246	10,080	19,332	2,510,246
Series C convertible preferred units	5,000,000	4,972,115	32,348	32,488	4,972,115
Series C-1 convertible preferred units	2,520,000	2,504,099	17,607	18,270	2,511,608
Series D convertible preferred units	7,500,000	3,149,577	52,214	49,174	3,400,875
Series E convertible preferred units	11,000,000	10,493,767	74,811	75,000	10,493,767
	32,620,000	**27,629,804**	**$ 191,034**	**$ 202,264**	**27,888,611**

	Units		Carrying	Liquidation	Units issuable
December 31, 2020	**Authorized**	**Outstanding**	**Value**	**Preference**	**upon conversion**
Series A units	4,000,000	4,000,000	$ 3,974	$ 8,000	4,000,000
Series B units	2,600,000	2,510,246	10,080	19,332	2,510,246
Series C units	5,000,000	4,972,115	32,348	32,488	4,972,115
Series C-1 units	2,520,000	2,504,099	17,607	18,325	2,511,058
Series D units	7,500,000	3,149,577	52,214	53,102	3,380,906
Series E units	11,000,000	9,609,491	68,491	68,680	9,609,491
	32,620,000	**26,745,528**	**$ 184,714**	**$ 199,927**	**26,983,816**

The following provides a summary of the rights of the holders of convertible preferred and common units, prior to the Offering:

Conversion Rights

The holders of Preferred Units have the right to convert the Preferred Units at any time into common units at an initial conversion ratio of one-to-one, subject to certain adjustments. The Preferred Units will automatically convert into common units at the conversion rate in effect at that time immediately upon the closing of an IPO that results in total proceeds to the Company of at least $100.0 million.

Redemption rights

No Preferred Units or common units are unilaterally redeemable by either the unitholders or the Company; however, the Company’s Operating Agreement provides that upon any liquidation event such units shall be entitled to receive the applicable liquidation preference.

Net Income and Loss Allocation

Net income and loss shall be allocated to the Preferred Units in a manner that if the Company were to liquidate completely and in connection with such liquidation (i) sell all of its assets at their carrying values, defined as the fair market value, (ii) settle all of its liabilities to the extent of the available assets of the Company, and (iii) each Preferred Unit holder were to pay to the Company at that time the amount of any obligation then unconditionally due to the Company, then each Preferred Unit holder's capital account balance would correspond as closely as possible to the distributions that would result if the distributions to such Preferred Unit holders were made in accordance with the Operating Agreement.

Distributions

Distributions of the Company's assets to Preferred Unit holders or common unit holders shall be made with the approval of the Board of Managers and with sufficient working capital reserves retained. There shall be no distribution to the Preferred Unit holders until such time as the Company has earned gross revenues of $20.0 million on a cumulative basis (or such other lesser amount as unanimously approved by the board of managers). The Company has not declared any distributions to date.

After the Company earns $20.0 million and prior to $50.0 million in gross revenue on a cumulative basis, distributions are as follows:

- First, to the Preferred Unit holders, on a *pari passu* and pro rata basis, until the cumulative amount of distributions made with respect to each unit equals their aggregate capital contributions; and

- Second, to common unit holders pro rata in proportion to the number of common units held.

After the Company earns $50.0 million and prior to $100.0 million in gross revenue on a cumulative basis, distributions are as follows:

- First, to Preferred and common unit holders, on a *pari passu* basis and pro rata in proportion to the number of units, until the cumulative amount of distributions made with respect to each unit equals their aggregate capital contributions;

- Second, to Preferred Unit holders, on a *pari passu* basis and pro rata in proportion to the number of Preferred Units held, until they have been distributed an additional amount equal to their aggregate capital contributions; and

- Third, 100% to common unit holders, excluding common unit holders who were formerly Preferred Unit holders subject to automatic conversion of their Preferred Units.

After the Company earns $100.0 million in gross revenue on a cumulative basis, distributions are as follows:

- First, to the Preferred Unit holders, on a *pari passu* basis and pro rata in proportion to the number of preferred units, until the cumulative amount of distributions made with respect to each unit equals their original capital contribution, then until the cumulative amount made with respect to each unit equals their aggregate contribution; and

- Second, to Preferred Unit holders and common unit holders pro rata in proportion to the number of common units held assuming full conversion of Preferred Units to common units at the applicable conversion rate.

Liquidating Distributions

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, including a merger or sale of the Company ("Deemed Liquidation Event"), the amount to be paid for each class of unit is equal to the original price of the issuance, plus any declared but unpaid dividends. At June 30, 2021, the liquidation priority is as follows:

- First 100% to the holders of Series E units until they have been distributed an amount equal to their aggregate capital contributions less any amounts previously distributed to the Preferred Unit holders;

- Second 100% to the holders of Series D units, until they have been distributed an amount equal to their aggregate capital contributions less any amounts previously distributed to the Preferred Unit holders;

- Third 100% to the holders of Series A, B, C, C-1 units pari passu and pro rata in proportion to the number of Preferred Units held by each, until the holders of Series A units and Series B units have been distributed an amount equal to 200% of their aggregate capital contributions less any amounts previously distributed to the Preferred Unit holders and the holders of Series C units and C-1 units have been distributed an amount equal to their aggregate capital contributions less any amounts previously distributed to the Preferred Unit holders; and

- Thereafter, 100% to the holders of Series A, B, and common units pari passu and pro rata in proportion to the number of common units held by each, assuming full conversion of the Preferred Units into common units at the then-applicable conversion rate, as defined in the Operating Agreement.

Tax Distributions

Within ninety days of the end of each fiscal year, the Company will make a distribution to each holder of units out of any available cash of the Company an amount equal to the excess of the sum of:

- the product of any amount of net income and gain taxable at ordinary tax rates allocated with respect to each unit and the maximum marginal rate of federal, state and local income and employment tax applicable to an individual subject to tax with respect to such income or gain, and

- the product of the amount of net income and gain table at long-term capital gains rates allocated with respect to such unit and the maximum marginal rate of federal, state and local income and employment tax applicable to an individual subject to tax with respect to such income or gain, and

- in the event of allocation by the Company of net income or gain taxable at a rate other than the ordinary or long-term capital gains rates contemplated in clauses (i) and (ii) above, the product of the amount of such net income and gain taxable at such other rate allocated with respect to such unit and the maximum marginal rate of federal, state and local income and employment tax applicable to an individual subject to tax with respect to such income or gain, over the cumulative cash distributions previously made with respect to such unit.

No tax distributions were made during any of the periods presented.

Voting Rights

The holders of Preferred Units, on an as converted to common unit basis, and the holders of common units shall vote together and not as separate voting groups on all matters required or permitted to be voted on, consented to, or taken or approved by the unit holders of the Company.

Registration Rights

Under our investors' rights agreement, certain holders of our units have the right to demand that we file a registration statement or request that their units be covered by a registration statement that we are otherwise filing. Holders of the Company's Preferred Units have the right to request the Company to file certain registration statements with the Securities and Exchange Commission for the registration of shares related to the Preferred Units. The obligations of the Company regarding such registration rights include, but are not limited to, commercially reasonable efforts to cause such registration statement to become effective, keep such registration statement effective for up to 120 days, prepare and file amendments and supplements to such registration statement and the prospectus used in connection with such registration statement, and furnish to the selling holders copies of the prospectus and any other documents as they may reasonably request. The terms of the registration rights provide for the payment of certain expenses related to the registration of the shares, including a capped reimbursement of legal fees of a single special counsel for the holders of the shares, but do not impose any obligations for the Company to pay additional consideration to the holders in case a registration statement is subsequently withdrawn at the request of the holders.

Common Units

Holders of the Company's common units have no explicit redemption rights and vote on a one-to-one basis based on the number of common units held. Common units reserved for future issuance, consisted of the following as of:

Class of Units/Shares	June 30, 2021	December 31, 2020
Units reserved for conversion of outstanding Series A	4,000,000	4,000,000
Units reserved for conversion of outstanding Series B	2,510,246	2,510,246
Units reserved for conversion of outstanding Series C	4,972,115	4,972,115
Units reserved for conversion of outstanding Series C-1	2,511,608	2,511,058
Units reserved for conversion of outstanding Series D	3,400,875	3,380,906
Units reserved for conversion of outstanding Series E	10,493,767	9,609,491
Units reserved for Profit Interests, issued and outstanding	8,547,401	6,926,358
Units reserved for options, issued and outstanding	2,292,309	—
Units reserved for Profit Interests and options, authorized for future issuance	10,290	3,923,642
	38,738,611	**37,833,816**

9. Equity-Based Compensation

In 2016, the Company adopted the 2016 Equity Incentive Plan (the "Plan") under which the Board of Managers may issue options for common units, Profits Interests, and restricted common units to managers, consultants or other individuals who provide service to the Company. The Board of Managers has the authority to determine to whom Profits Interests will be granted, the number of options granted, and the Profits Interests threshold amount, which is the minimum amount determined by the Board of Managers in its reasonable discretion to be necessary to cause such interests to be treated as Profits Interests ("Threshold Amounts"). In 2020, the Board of Managers approved an additional 2,000,000 common units to be reserved under the Plan for issuance as Profit Interests. Effective April, 2021, in anticipation of the Offering the Company ceased granting Profits Interests and began to issue options for common units out of the remaining pool. At June 30, 2021 there was a total of 10,850,000 common units were reserved under the Plan, and 10,290 common units remained available for future grants.

Immediately upon receipt of a Profits Interests award, the recipient will have no initial capital account balance and the Profits Interests received shall not entitle such recipient to any portion of the capital of the Company at the time of such recipient's admission to the Company as an unitholder member, such that if the Company's assets were sold at fair market value immediately after the grant to such recipient of Profits Interests and the proceeds distributed in complete liquidation of the Company, the Profits Interests received would entitle such recipient to receive no portion of those proceeds. Additionally, the Company shall not make a distribution with respect to any Profits Interests unless the Company has made aggregate distributions to each interest subject to a lower or no Profits Interests Threshold Amount. The common units underlying each Profits Interests award entitle the holder, upon a sale or other specified capital transaction (as set forth in the Operating Agreement), to participate in a portion of the profits and appreciation in the equity value of the Company arising after the date of grant, as determined in reference to the Profits Interests Threshold Amount set forth in each award agreement.

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

	Number of Profits Interests		Weighted Average Grant Date Fair Value	Profits Interests Threshold
Balance at December 31, 2020	6,926,358	$	1.63	$1.44 - $2.29
Forfeitures	(235,957)	$	2.04	$1.45 - $2.29
Profit Interests grants	1,857,000	$	2.00	$1.99 - $2.13
Balance at June 30, 2021	8,547,401	$	1.70	$1.44 - $2.29

All Profits Interests are subject to a performance-based condition, which is subject to the achievement of certain revenue targets or a liquidation of the Company, and a service condition subject to the holder's continued employment with Rani or ICL. An IPO accelerates the service condition vesting of the Profits Interests. No equity distribution to ICL or equity-based compensation expense to the Company have been recorded since inception, as the Company has concluded that achievement of the performance-based condition is not considered probable as of June 30, 2021.

As of June 30, 2021, there was $14.5 million of unrecognized equity-based compensation expense and distribution of equity to ICL associated with the total of all Profits Interests subject to performance conditions.

Options for Common Units

During the second quarter of 2021, the Company granted options to acquire the Company's common units to certain executives and members of the Board of Managers. These options for common units vest based on the grantees continued services over a three to four year period.

A summary of options for common units activity during the periods indicated is as follows:

	Number of Unit Option Awards	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2020	—	—		
Options for common units granted	2,292,309	4.99	10.0	—
Balance at June 30, 2021	2,292,309	4.99	10.0	
Exercisable at June 30, 2021	—	—	—	—
Nonvested at June 30, 2021	2,292,309	4.99	10.0	—

As of June 30, 2021, there was $7.6 million of unrecognized equity-based compensation expense related to options for common units which is expected to be recognized over a weighted-average period of approximately 3.5 years.

The following table summarizes the components of equity-based compensation expense resulting from the grant of options for common units, recorded in the Company's condensed consolidated statement of operations and comprehensive loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 61	—	$ 61	—
General and administrative	221	—	221	—
Total equity-based compensation	$ 282	—	$ 282	—

10. Commitments and Contingencies

Leases

Rani pays for the use of its office, laboratory and manufacturing facilities in San Jose, California as part of the services agreement with ICL (see Note 6) which is accounted for as an operating lease with an implied renewal option into 2025. Rent expense incurred with ICL was $0.4 million for both of the six months ended June 30, 2021 and 2020, respectively.

Legal Proceedings

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

11. Long-Term Debt

Convertible Notes

In September 2020, the Company entered into a secured convertible loan agreement (the "Loan and Security Agreement" or the "Loan") with Avenue Venture Opportunity Fund L.P. ("Avenue"), whereby the Company could borrow up to a maximum of $10.0 million, with $3.0 million being immediately available. The remaining $7.0 million available could be borrowed if Avenue received evidence of at least $40.0 million of net cash proceeds from the sale or issuance of securities to existing investors, or upfront

payments in connection with strategic partnerships by March 31, 2021. The Company opted not to drawn down this additional amount, and the option has since expired undrawn. Avenue has the right, while the Loan is outstanding, to convert, at any time, an amount up to $3.0 million of the outstanding loan principal into the previous round of preferred units issued by the Company, currently Series E preferred, or the then current series of units subject to the Company's most current round of financing, at a 20% premium of the latest preferred unit offering price. In exchange for access to this facility, the Company agreed to issue warrants exercisable into the Company's preferred units amounting to $0.9 million; the Company subsequently granted 118,929 Series E warrants with an exercise price of $7.1471 per unit (Note 7).

In the event of a qualified financing, whereby the Company raises capital of at least $75.0 million of total gross proceeds in cash, the Series E warrant will automatically convert into preferred units at a price equal to the issue price per share of the shares issued in the qualified financing and on the same terms and conditions of such qualified financing.

The Loan is interest only until September 2021 and bears interest at a variable rate of interest per annum, compounded monthly until its maturity date of September 2023, at which time all outstanding principal and interest will become due and payable in cash if not already converted. The Company's obligations under the Loan are secured by a first priority security interest in substantially all of its assets. The Loan includes customary events of default, including instances of a material adverse change in the Company's operations, which may require prepayment of the outstanding Loan.

At June 30, 2021 and December 31, 2020 the effective interest rate on the Loan was 20.56%.

The Loan 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 June 30, 2021 and December 31, 2020.

The Loan and Security Agreement contains negative and affirmative covenants, including covenants that restrict the ability of the Company and its current and future subsidiaries ability to, among other things, incur or prepay existing indebtedness, pay dividends or distributions, dispose of assets, engage in mergers and consolidations, make acquisitions or other investments, and make changes in the nature of the business. The Loan and Security Agreement also contains certain objective events of default, including, without limitation, nonpayment of principal, interest or other obligations, violation of the covenants, insolvency, court ordered judgments, and change in control. The Loan and Security Agreement also requires the Company to provide audited consolidated financial statements to the lenders no later than 120 days after year-end.

The Company was in compliance with all of the debt covenants under the Loan and Security Agreement as of June 30, 2021 and there were no events of default during the six months ended June 30, 2021. In July 2021, the Company repaid the Loan in full (see Note 14). Due to the Company having the intent and ability to repay the Loan as of June 30, 2021, such Loan has been classified as a current liability as of June 30, 2021.

Paycheck Protection Program Loan

In April 2020, the Company received a $1.3 million small business loan under the Paycheck Protection Program ("PPP Loan") as part of the CARES Act. The PPP Loan matures in April 2022, and bears interest at a rate of 1.0% per annum. The PPP Loan is evidenced by a promissory note, which contains customary events of default relating to, among other things, payment defaults and breaches of representations and warranties. The PPP Loan may be prepaid by us at any time prior to maturity with no prepayment penalties.

The Company has used all proceeds from the PPP Loan to retain employees, maintain payroll and make lease and utility payments. The Company believes it would qualify for forgiveness for all of the loan amount. The Company was in compliance with all of the debt covenants under the PPP Loan and there were no events of default as of June 30, 2021. In September 2021, the Company repaid the PPP Loan in full (see Note 14).

As of June 30, 2021, future principal payments for the Company's debt are as follows (in thousands):

2021 (remaining six months)	$ 1,350
2022	1,779
2023	1,125
Total principal payments	4,254
Less: amount representing debt discount	(385)
Add: amount representing interest	15
Present value of remaining debt payments	3,884
Less: current portion	(3,884)
Total long-term debt, less current portion	$ -

12. Income Taxes

The Company is treated as a flow-through entity for federal and state income tax purposes. The income or loss generated by this entity is not taxed at the LLC level. As such, the Company's income tax provision consists solely of the activity of its taxable subsidiary, RMS, which is taxed as a corporation for federal income tax purposes.

The Company's effective income tax rate was (0.21)% and (0.17)% for the three and six months ended June 30, 2021, and (0.21)% for each of the three and six months ended June 30, 2020, respectively. The change in the Company's effective income tax rate for the three and six months ended June 30, 2021 compared to the three and six months ended June 30, 2020 was primarily driven by the change in net income and the ability to utilize the tax credits available to the Company.

There were no material changes to uncertain tax positions for the three and six months ended June 30, 2021 and 2020, respectively, and the Company does not anticipate material changes within the next 12 months.

13. Net Loss Per Unit

The following table sets forth the computation of basic and diluted net loss per unit (in thousands, except for units and per unit data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	$ (5,485)	$ (2,714)	$ (11,083)	$ (8,064)
Denominator:				
Weighted average common units outstanding—basic and diluted	46,896,280	46,890,280	46,896,081	46,890,280
Net loss per unit—basic and diluted	$ (0.12)	$ (0.06)	$ (0.24)	$ (0.17)

The following table shows the total outstanding securities considered anti-dilutive and therefore excluded from the computation of diluted net loss per unit:

	Six Months Ended June 30,	
	2021	2020
Preferred units	27,888,611	17,084,696
Units reserved for Profits Interests	8,547,401	6,937,348
Units reserved for options for common units	2,292,309	—
Common unit warrants	223,315	229,315
Preferred unit warrants	118,929	107,357
Total	39,070,565	24,002,325

The impact of the conversion of the Loan has also been excluded as it would be anti-dilutive.

14. Subsequent Events

Repayment of Convertible Notes

In July 2021, the Company repaid in full the $3.0 million of principal and approximately $0.5 million of final payment and fees under the Loan and Security Agreement. Avenue Capital also waived their right to convert the outstanding principal into Series E Preferred Units.

Organization Transactions

In August 2021, and in connection with the completion of the Offering, the Company amended and restated its operating agreement (the "Rani LLC Agreement") to appoint Rani Holdings as the sole managing member of the Company 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 the Company into economic nonvoting Class A units ("Class A Units") and an equal number of voting noneconomic Class B units ("Class B Units") and (ii) all Profits Interests into Class A Units (the Class A Units and Class B Units are collectively referred to as the "LLC Interests"). In connection with the closing of the initial public offering, each LLC interest was exchanged 1 for 0.5282 as determined and predicated on the initial public offering price of Rani Holdings Class A common stock.

Certain holders of the Company's Class A Units (the "Former LLC Owners") immediately exchanged all of their Class A Units for 12,047,925 shares of Rani Holdings Class A common stock in connection with the Offering. The remaining individuals and entities that continued to own LLC Interests ("the Continuing LLC Owners") received 29,290,391 shares of Rani Holdings Class B common stock, other than those that did not tender their units, and may, subject to the terms of the amended and restated Rani LLC Agreement, exchange their LLC Interests for shares of Rani Holdings' Class A common stock on a one to one basis with a corresponding number of such shares of Rani Holdings Class B common stock; provided that, at Rani Holdings' election, Rani Holdings 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 its Class A common stock for each LLC Interest redeemed. Certain individuals who continue to own interests in Rani LLC but do not hold shares of our Class B common stock can exchange their units for 1,545,811 shares of our Class A common stock. Any shares of Class B common stock will be cancelled on a one-for-one basis if the Company, at the election of the Continuing LLC Owners, redeems or exchanges such LLC Interests 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 that otherwise would not have been available. Increases in tax basis resulting from such exchanges may reduce the amount of tax that Rani Holdings 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.

Rani Holdings Initial Public Offering

In August 2021, Rani Holdings closed an initial public offering by selling 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 $73.7 million in net proceeds, after deducting underwriting discounts, offering costs and commissions.

The Company currently issued 7,666,667 new Class A common units that Rani Holdings subsequently purchased using the proceeds from its IPO.

2016 Equity Incentive Plan

The Rani Therapeutics, LLC 2016 Plan was terminated in July 2021 concurrent with the adoption of Rani Holdings 2021 Equity Incentive Plan. Outstanding awards granted under the 2016 Plan remain outstanding, subject to the terms of our 2016 Plan and award agreements.

Repayment of PPP Loan

In September 2021, the Company repaid in full the $1.3 million of principal and interest related to the PPP Loan.

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 interim condensed consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q, and our final prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, dated August 2, 2021 (the "Prospectus"). 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. You should carefully read the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" sections of this document for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

The following discussion contains references to calendar year 2020 and the six months ended June 30, 2020 and June 30, 2021, which represents the condensed consolidated financial results of Rani Therapeutics, LLC ("Rani") and its subsidiary for the year ended December 31, 2020 and the six months ended June 30, 2020 and 2021, respectively. Unless we state otherwise or the context otherwise requires, the terms "we," "us," "our," and "Rani" and similar references refers to Rani and its consolidated subsidiary.

Rani Therapeutics Holdings, Inc. ("Rani Holdings") was incorporated in April 2021 for the purpose of facilitating an initial public offering in order to carry on the Company's business. In August 2021, Rani Holdings completed an initial public offering (the "Offering") by selling 7,666,667 shares of its Class A common stock, including shares issued subsequently pursuant to the exercise in full of the underwriters' option, for cash consideration of $11.00 per share and received approximately $73.7 million in net proceeds, after deducting underwriting discounts, offering costs and commissions. The following discussion does not include the effects of the Offering, as it was completed subsequent to June 30, 2021.

Overview

We are a clinical stage biotherapeutics company advancing technologies to enable the development of orally administered biologics. We have developed the RaniPill capsule, which is our novel, proprietary and patented platform technology, intended to replace subcutaneous or IV injection of biologics with oral dosing. The RaniPill capsule is an orally ingestible pill approximately the size of a "000" capsule (or similar to the size of a standard fish oil or calcium pill) that is designed to automatically administer a precise therapeutic dose of medication upon deployment in the small intestine. To date, we have successfully conducted several preclinical and clinical studies to evaluate safety, tolerability and bioavailability using the RaniPill capsule. Our development efforts have enabled us to construct an extensive intellectual property portfolio that we believe provides us a competitive advantage. Our pipeline includes five core product candidate programs. Additionally, we envision complementing these core programs with robust partnering activities to maximize the value inherent in the RaniPill capsule.

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 our preferred units and the issuance of convertible promissory notes, with aggregate gross proceeds of $282.5 million, as well as revenue generated from evaluation agreements. We expect that our cash and cash equivalents of $69.3 million as of June 30, 2021 and net proceeds of $73.7 million from the IPO will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next twelve months.

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.

Since our inception, we have incurred significant losses and negative cash flows from operations. Our net losses were $5.5 million and $11.1 million for the three and six months ended June 30, 2021, respectively. As of June 30, 2021, we had an accumulated deficit of $125.1 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, 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.

Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide, such as those resulting from the ongoing COVID-19 pandemic. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from commercial product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce or terminate our operations.

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

COVID-19 Pandemic

Since it was reported to have surfaced in late 2019, COVID-19 has spread across the world and has been declared a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have intensified and governments around the world, including in the United States, Europe and Asia, have implemented precautions such as travel restrictions, social distancing requirements, and stay-at-home orders. As a result, the current COVID-19 pandemic has presented a substantial global public health and economic challenge and is affecting our employees and business operations, as well as contributing to significant volatility and negative pressure on the U.S. economy and in financial markets. The COVID-19 pandemic has and may continue to impact the Company's third-party manufacturers and suppliers, which could disrupt its supply chain or the availability or cost of materials. The effects of the public health directives and the Company's work-from-home policies may negatively impact productivity, disrupt its business, and delay clinical programs and timelines and future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on the Company's ability to conduct business in the ordinary course. These and similar, and perhaps more severe, disruptions in the Company's operations could negatively impact business, results of operations and financial condition, including its ability to obtain financing.

We have initiated, and may take additional, temporary precautionary measures intended to help ensure our employees' well-being and minimize business disruption. For the safety of our employees and their families, we have temporarily reduced the presence of our employees in our office and continue to rely on third parties to conduct many of the experiments and preclinical studies for our research programs. Certain third-party service providers have also experienced shutdowns or other business disruptions. The extent to which the COVID-19 pandemic may affect our business, operations and development timelines and plans, including the resulting impact on expenditures and capital needs, remains uncertain.

Organizational Transactions

Rani Holdings was incorporated in April 2021 and formed for the purpose of facilitating the Offering in order to carry on the Company's business. In connection with the Offering, Rani Holdings became a holding company and its principal asset is the Class A common units of Rani that it owns. As the sole managing member of the Company, Rani Holdings operates and controls all of the Company's operations, and through Rani and its subsidiary, conducts all of Rani's business and the financial results of Rani and its consolidated subsidiary will be included in the consolidated financial statements of Rani Holdings.

Rani has been, and after the Offering 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 , 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 LLC Interests in Rani, Rani Holdings is subject to U.S. federal, state and local income taxes with respect to its allocable share of any taxable income of Rani and will be taxed at the prevailing corporate tax rates. In addition to tax expenses, we also will incur expenses related to our operations and we are required to make payments under the Tax Receivable Agreement with certain of the Continuing LLC Owners. Due to the uncertainty of various factors, we cannot estimate the likely tax benefits we will realize as a result of LLC Interests exchanges, and the resulting amounts we will likely pay out to LLC Unitholders pursuant to the Tax Receivable Agreement; however, we estimate that such payments may be substantial in the event we are profitable.

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 has been derived from the evaluation agreements, which are recorded as contract revenue. As of June 30, 2021, 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 we may enter into 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 and commercialize the capsule. Because of the numerous risks and uncertainties associated with product development and regulatory approval, we are unable to predict the amount, timing or whether we will be able to obtain commercial product revenue.

Operating Expenses

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

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 commercialize the RaniPill capsule. 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 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 expenses.

Internal expenses, consisting of:

- expenses including salaries, bonuses, equity-based compensation and benefits for personnel engaged in 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. We expect our research and development expenses to increase significantly in the foreseeable future as we continue to invest in research and development activities related to developing the RaniPill capsule, 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 upon successful completion of clinical trials, and incur expenses associated with hiring additional personnel to support our 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 is highly uncertain, and we may never succeed in achieving regulatory approval for the RaniPill capsule.

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, 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 expenses, marketing expenses, and facility-related expenses, 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. 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 insurance costs, and investor and public relations costs.

Other Income (Expense), Net

Other income (expense), net primarily consists of interest income on our cash and cash equivalents and income (expense) associated with re-measurements of the estimated fair value of preferred unit warrants.

Relationship with InCube Labs

Services Agreements

In January 2019, the Company entered into a one year service agreement with ICL, the majority holder of the Company's common units and a related party. This agreement was amended in January 2020 to extend the period for an additional year and expired in December 2020. The Company is presently operating under a service agreement with ICL executed in June 2021, retroactive to January 1, 2021. The Company or ICL may terminate services under the service agreement upon 60 days' notice to the other party, except for occupancy which requires six months' notice. The service agreement specifies the scope of services to be provided by ICL as well as the methods for determining the costs of services for the year ended December 31, 2021. Costs are billed on a monthly basis and based upon the hours incurred by ICL employees working on behalf of Rani as well as allocations of expenses based upon Rani’s utilization of ICL’s facilities and equipment.

In June 2021, RMS entered into the RMS-ICL Service Agreement effective January 1, 2021, pursuant to which ICL agreed to rent a specified portion of its facility to RMS. Additionally, RMS and ICL agreed to provide personnel services to the other upon requests based on rates specified in the agreement. The RMS-ICL Service Agreement has a 12-month term and will automatically renew for successive 12-month periods unless terminated. For the six months ended June 30, 2020 and 2021, RMS charged ICL $0.2 million and $0.3 million for services performed, respectively, and such amounts charged were recorded as a reduction to research and development expense in the condensed consolidated statement of operations and comprehensive loss.

Our eligible employees are permitted to participate in ICL's 401(k) Plan ("401(k) Plan"). Participation in the 401(k) Plan is offered for the benefit of our employees, including our named executive officers, who satisfy certain eligibility requirements.

All of our facilities are owned by an entity affiliated with one of our directors, who is also the owner of ICL. Rani pays for the use of these facilities through the service agreement with ICL.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 123	$ (63)	$ 156	$ 121
General and administrative	184	207	366	451
Total	$ 307	$ 144	$ 522	$ 572

Financing activity

From inception to December 31, 2017, we advanced funds to ICL, and ICL made payments directly to certain vendors on behalf of us. We have reimbursed ICL for all such payments at cost on a monthly basis. In June 2017, we converted the outstanding advances of $6.6 million to ICL into notes receivable. The notes provided for interest at 1.97% compounded annually, loan fees of 2.75% and were payable upon demand to us any time after January 1, 2024. During 2020, we received $1.0 million in payments for interest and repayment of principal on the ICL notes receivable. During the six months ended June 30, 2020, payments for interest and repayment of principal on the ICL note receivable was insignificant. During the six months ended June 30, 2021, we received $1.7 million for interest and principal on the ICL notes receivable. As of December 31, 2020, $1.7 million of the notes were outstanding. As of June 30, 2021, the outstanding balance, including all accrued interest, was fully repaid.

In December 2020, we amended the terms of certain expired warrants to purchase Series B units (the "Series B Warrants"), issued to InCube Ventures II, LP ("ICV II"), a related party and entity affiliated with ICL, by extending its exercise period for an additional two years. In December 2020, ICV II elected to cashless exercise all of their Series B Warrants and Rani issued 51,341 Series B units. There were no Series B Warrants outstanding at June 30, 2021.

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 License Agreement, we will 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 U.S. patent families from ICL by making a one-time payment of $250,000 to ICL for each U.S. 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, 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 a related party, pursuant to which we granted ICL a non-exclusive, fully-paid license under specified patents that were assigned from ICL to the Company. 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.

Future Public Company Expenses

As a result of the Offering, we expect our operating expenses to increase. We expect our accounting, legal and personnel-related expenses and directors' and officers' insurance costs reported within general and administrative to increase as we establish more comprehensive compliance and governance functions, maintain and review internal controls over financial reporting in accordance with the Sarbanes-Oxley Act of 2002 and prepare and distribute periodic reports as required by the rules and regulations of the SEC. As a result, our historical results of operations may not be indicative of our results of operations in future periods.

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

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

	Three Months Ended June 30,	
	2021	2020
Contract revenue	$ 1,961	$ 60
Operating expenses		
Research and development	3,759	2,558
General and administrative	3,460	892
Total operating expenses	$ 7,219	$ 3,450
Loss from operations	(5,258)	(3,390)
Other income (expense), net		
Interest income	13	12
Interest expense and other, net	(169)	(2)
Change in estimated fair value of preferred unit warrant	(70)	672
Loss before income taxes	(5,484)	(2,708)
Income tax expense	(1)	(6)
Net loss and comprehensive loss	$ (5,485)	$ (2,714)

Contract Revenue

Contract revenue was $2.0 million and $0.1 million for the three months ended June 30, 2021 and 2020, respectively, which was attributable to our evaluation agreement with Takeda. In May 2021, we received notice from Takeda as to their intent to terminate the contract for convenience. The termination of the contract was considered a modification of the arrangement, and the deferred revenue remaining of $2.0 million under this agreement was fully recognized in the three months ended June 30, 2021.

Research and Development Expenses

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

	Three Months Ended June 30,	
	2021	2020
Payroll, equity-based compensation and related benefits	$ 2,679	$ 1,328
Facilities, materials and supplies	853	498
Third-party services	173	707
Other	54	25
Total	$ 3,759	$ 2,558

Research and development expenses were $3.8 million for the three months ended June 30, 2021, compared to $2.6 million for the three months ended June 30, 2020. The change in research and development expense was primarily related to an increase of $1.4 million in salaries, equity-based compensation and related benefit costs due to an increase in headcount, and an increase of laboratory supplies of $0.3 million, partially offset by a reduction in third-party services of $0.5 million associated with the development of our manufacturing processes that occurred in 2020 and did not recur in 2021.

General and Administrative Expenses

General and administrative expenses were $3.5 million for the three months ended June 30, 2021, compared to $0.9 million for the three months ended June 30, 2020. During the three months ended June 30, 2021, our professional and consulting services expense increased by $1.4 million primarily due to the costs associated with preparing to operate as a public company, and our payroll, equity-based compensation and related benefits increased by $0.9 million due to an increase in headcount.

Other Income (Expense), Net

Other expense, net was $0.2 million for the three months ended June 30, 2021, which related to $0.1 million of interest expense on the debt incurred at the end of 2020 and $0.1 million due to the increase in the estimated fair value of our Series E preferred unit warrants. Other income, net for three months ended June 30, 2020 was primarily due to change in estimated fair value of our Series B preferred unit warrants.

Comparison of the Six Months Ended June 30, 2020 and 2021

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

	Six Months Ended June 30,	
	2021	**2020**
Contract revenue	$ 2,717	$ 143
Operating expenses		
Research and development	7,106	6,618
General and administrative	6,067	2,299
Total operating expenses	$ 13,173	$ 8,917
Loss from operations	(10,456)	(8,774)
Other income (expense), net		
Interest income	60	74
Interest expense and other, net	(357)	(2)
Change in estimated fair value of preferred unit warrant	(286)	655
Loss before income taxes	(11,039)	(8,047)
Income tax expense	(44)	(17)
Net loss and comprehensive loss	$ (11,083)	$ (8,064)

Contract Revenue

Contract revenue was $2.7 million and $0.1 million for the six months ended June 30, 2021 and 2020, respectively, which was attributable to our evaluation agreement with Takeda. $0.7 million of revenue in 2021 related to the timing of work performed under the agreement. In May 2021, the Company received notice from Takeda as to their intent to terminate the contract for convenience. The termination of the contract was considered a modification of the arrangement, and the deferred revenue remaining of $2.0 million under this agreement was fully recognized in the second quarter of 2021.

Research and Development Expenses

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

	Six Months Ended June 30,	
	2021	2020
Payroll, equity-based compensation and related benefits	$ 4,874	$ 3,318
Facilities, materials and supplies	1,536	1,203
Third-party services	359	2,063
Other	337	34
Total	$ 7,106	$ 6,618

Research and development expenses were $7.1 million for the six months ended June 30, 2021, compared to $6.6 million for the six months ended June 30, 2020. The change in research and development expense was primarily related to an increase of $1.8 million in salaries, equity-based compensation, and related benefit costs due to an increase in headcount, and an increase in laboratory supplies of $0.3 million, partially offset by a reduction in third-party services of $1.8 million associated with the development of our manufacturing processes that occurred in 2020 and did not recur in 2021.

General and Administrative Expenses

General and administrative expenses were $6.1 million for the six months ended June 30, 2021, compared to $2.3 million for the six months ended June 30, 2020. During the six months ended June 30, 2021, our professional and consulting services expense increased by $2.4 million primarily due to the costs associated with preparing to operate as a public company, and our payroll, equity-based compensation and related benefits increased by $1.3 million due to an increase in headcount.

Other Income (Expense), Net

Other expense, net was $0.6 million for the six months ended June 30, 2021, which primarily related to $0.4 million of interest expense on the debt incurred at the end of 2020 and $0.3 million due to the increase in the estimated fair value of our Series E preferred unit warrants. Other income, net for six months ended June 30, 2020 was primarily due to the change in estimated fair value of our Series B preferred unit warrants.

Liquidity and Capital Resources

Source of Liquidity

Since our inception in 2012, 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 initial public offering ("IPO"), private placements of our preferred units and the issuance of convertible promissory notes, with aggregate gross proceeds of $282.5 million, as well as revenue generated from evaluation agreements. As of June 30, 2021, we had cash and cash equivalents of $69.3 million. In August 2021 we raised net proceeds of $73.7 million from the IPO.

In April 2020, we received loan proceeds in the amount of approximately $1.3 million under the PPP, established pursuant to the CARES Act, with Comerica Bank as the lender (the “PPP Loan”). We have used this loan for the eligible purposes, including payroll, benefits, rent and utilities. The loan bears interest at 1% per annum. In September 2021, the Company repaid in full the $1.3 million of principal and interest related to the PPP Loan.

In September 2020, we entered into a secured convertible loan agreement (the “Avenue Loan Agreement”) with Avenue Venture Opportunities Fund, L.P., for loan proceeds of up to $10.0 million. As of June 30, 2021, we had drawn down $3.0 million under the Avenue Loan Agreement. The Loan bears interest at a variable rate per annum equal to the sum of (i) the greater of (A) the Prime Rate and (B) three and one-quarter percent (3.25%), plus (ii) eight percent (8.00%), compounded monthly until its maturity date of September 1, 2023, at which time all outstanding principal and interest became due and payable in cash if not already converted. Our obligations under the Avenue Loan Agreement are secured by a first priority security interest in substantially all of our assets. In connection with the Avenue Loan Agreement, we have issued warrants of 118,929 units of Series E preferred units (the Series E

Warrants). The Series E Warrants are exercisable for a period of seven years from the date of grant at an exercise price of $7.1471 per unit. The loan is convertible at the option of the holder into our Series E convertible preferred units. We were in compliance with the covenants under the loan, and there were no events of default for the six months ended June 30, 2021. As of June 30, 2021, we have elected not to exercise our option to draw down the remaining $7.0 million of the Avenue Loan Agreement. In July 2021, we repaid in full the $3.0 million of principal and approximately $0.5 million of final payment and fees under the Avenue Loan Agreement.

In October 2020, we entered into the Fourth Amended and Restated Operating Agreement, which authorized the sale and issuance of up to 10,493,767 Series E Preferred Units. As of June 30, 2021, we had issued the total authorized amount at a price of $7.1471 for gross proceeds of $75.0 million.

After completion of the Offering, Rani Holdings became a holding company and has no material assets other than its ownership of LLC Interests. Rani Holdings has no independent means of generating revenue. The limited liability company agreement of Rani that went into effect at the closing the Offering provides that certain distributions will be made to cover the taxes of the owners of LLC Interests and Rani Holdings' obligations under the Tax Receivable Agreement which was entered into with certain of the Continuing LLC Owners.

Tax Receivable Agreement

We entered into a Tax Receivable Agreement with certain of the Continuing LLC Owners in August 2021 in connection with the Offering. 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 Rani Holdings or us 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 Rani Holdings 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. Due to the uncertainty of various factors, we cannot precisely quantify the tax benefits we may realize as a result of LLC Interest exchanges and the resulting amounts we may need to pay out to certain of the Continuing LLC Owners pursuant to the Tax Receivable Agreement; however, we estimate that such payments may be substantial.

Future Funding Requirements

Based on our current operating plan, as of September 10, 2021, 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 because the extent to which we may enter into strategic collaborations or other arrangements with third parties for development of the RaniPill capsule 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. In addition, we expect to incur additional costs once we are operating as a public company.

We may seek to raise capital through equity offerings or debt financings, collaboration agreements, or other arrangements with other companies, or through other sources of financing. 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 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.

Cash Flows

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

	Six Months Ended June 30,	
	2021	2020
Net cash used in operating activities	$ (9,676)	$ (8,930)
Net cash used in investing activities	(235)	(944)
Net cash provided by financing activities	6,167	1,254
Net decrease in cash and cash equivalents	$ (3,744)	$ (8,620)

Operating Activities

Net cash used in operating activities for the six months ended June 30, 2021 was $9.7 million, which was primarily attributable to a net loss of $11.1 million, partially offset by non-cash depreciation and amortization of $0.3 million, and change in the estimated fair value of our preferred unit warrant liability of $0.2 million, equity-based compensation expense of $0.7 million. Additionally, our operating assets and liabilities increased by $0.2 million.

Net cash used in operating activities for the six months ended June 30, 2020 was $8.9 million, which was primarily attributable to a net loss of $8.1 million, partially offset by non-cash depreciation and amortization of $0.3 million, a decrease in accounts payable of $1.6 million, and the payment of the related party payable balance of $1.6 million.

Investing Activities

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

For the six months ended June 30, 2020, net cash used in investing activities was $0.9 million, consisting solely of purchases of property and equipment.

Financing Activities

For the six months ended June 30, 2021, cash provided by financing activities was approximately $6.2 million, consisting of 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 payment of deferred offering costs of $1.9 million.

For the six months ended June 31, 2020, cash provided by financing activities was approximately $1.3 million, consisting solely of proceeds from the Paycheck Protection Program Loan.

Critical Accounting Policies, Significant Judgments and Use of Estimates

This discussion and analysis of financial condition and results of operation is based on our unaudited 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 critical accounting policies and estimates are discussed in the Prospectus. There have been no material changes in the Company’s critical accounting policies or estimates from those set forth in the Prospectus.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under the rules of the SEC.

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 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 June 30, 2021.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during the three months ended June 30, 2021 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.

Summary of Risk Factors

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the SEC before making investment decisions regarding our Class A common stock. See "Special Note Regarding Forward-Looking Statements." Unless we state otherwise or the context otherwise requires, the terms "we," "us," and "our," and similar references in this Section "Risk Factors" and in Part II – Other Information refers to Rani Therapeutics Holdings, Inc. and its consolidated subsidiaries, Rani Therapeutics, LLC and Rani Management Systems, Inc.

- We have a very limited operating history, have incurred operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- 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.
- 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.
- We are early in our development efforts and have only one product candidate, RT-101, the RaniPill capsule containing octreotide, in early clinical development. All of 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.
- 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. Further, we have never conducted a Phase 2 or Phase 3 clinical trial or submitted an application for marketing authorization.
- As an organization, we recently completed our first Phase 1 clinical trial, have not submitted an investigational new drug application ("IND") to the FDA and we have never conducted later-stage clinical trials or submitted a Biologics License Application ("BLA"), and may be unable to do so for any of 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.
- Product candidates comprising a biologic 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. 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 have limited clinical data on our product candidates to indicate whether they are safe or effective for long-term use in humans.
- We have conducted and may in the future conduct clinical trials for current or future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.
- The COVID-19 pandemic could adversely impact our business including our ongoing and planned preclinical studies and clinical trials.

- We face significant competition from other biotherapeutics and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- Our future success depends on our ability to retain our executive officers and to attract, retain and motivate highly qualified personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- Our commercial success may depend in part on our ability to build and maintain our intellectual property portfolio.
- We are a holding company and our principal asset is our interest in Rani. Accordingly, we will depend on distributions from Rani to pay our taxes, expenses (including payments under the Tax Receivable Agreement) and dividends. Rani's ability to make such distributions may be subject to various limitations and restrictions.
- Rani may make distributions of cash to us substantially in excess of the amounts we use to make distributions to our stockholders and pay our expenses (including our taxes and payments under the Tax Receivable Agreement). To the extent we do not distribute such excess cash as dividends on our Class A common stock, the Continuing LLC Owners would benefit from any value attributable to such cash as a result of their ownership of Class A common stock upon an exchange or redemption of their LLC Interests.
- The multi-class structure of our common stock has the effect of concentrating voting control, which will limit your ability to influence the outcome of important transactions, including a change in control.
- Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval and may prevent other stockholders from influencing significant corporate decisions.

Risk Factors

Investing in our Class A common stock involves a high degree of risk. You should carefully consider the risks described below, including our consolidated financial statements and related notes, before investing in our Class A common stock. While we believe that the risks and uncertainties described below are the material risks currently facing us, additional risks that we do not yet know of or that we currently think are immaterial may also arise and materially affect our business. If any of the following risks materialize, our business, financial condition and results of operations could be adversely affected. In that case, the trading price of our Class A common stock could decline. You should consider all of the risk factors described when evaluating our business.

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

We have a very limited operating history, have incurred operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

Biologics delivery is a highly speculative undertaking and involves a substantial degree of risk. We are an early clinical stage biopharmaceutical company with a very limited operating history upon which you can evaluate our business and prospects. We were formed in 2012, and to date, we have devoted the majority of our resources to research and development, manufacturing automation and scaleup, and establishing our intellectual property portfolio. RT-101, our most advanced product candidate, is in early clinical development, while our other product candidates remain in the formulation and preclinical development. We have not yet demonstrated an ability to successfully complete pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biologics delivery products.

We have incurred significant operating losses since our formation in 2012. Our net loss for the year ended December 31, 2020 and the six months ended June 30, 2021 was approximately $16.7 million and $11.1 million, respectively. As of June 30, 2021, we had an accumulated deficit of $125.1 million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders, deficit and working capital. The majority of our losses have resulted from expenses incurred in connection with research and development, manufacturing automation and scaleup, and establishing our intellectual property portfolio. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue incurring significant research, development, manufacturing and other expenses related to our ongoing business operations and product development, and as a result, we expect to continue incurring losses for the foreseeable future. We also expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates.

We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and our product candidates are in preclinical and early stage clinical trials. If any of our product candidates fail in preclinical studies or clinical trials or do not gain regulatory approval, or even if approved, fail to achieve market acceptance, we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the market price of our Class A common stock and our ability to raise capital and continue operations.

If one or more of our product candidates is approved for commercial sale and we retain commercial rights, we anticipate incurring significant costs associated with manufacturing and commercializing such approved product. Therefore, even if we are able to generate revenue from the sale of any approved product, we may never become profitable.

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 completed a Phase 1 clinical trial of our most advanced product candidate, RT-101, in Australia, and have completed preclinical studies of other product candidates. We plan to initiate Phase 1 clinical trials of certain of these product candidates in 2022 and in 2023. 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 conducted a Phase 1 clinical trial of RT-101 in healthy volunteers, conducted or are in the process of conducting preclinical studies of other product candidates, and are preparing to conduct Phase 1 clinical trials of certain of these product candidates, which we plan to initiate in 2022. In addition, our initial goal is 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 biologics for use within the RaniPill capsule and, if we are successful, to commercialize any of our current product candidates. If the FDA or any comparable foreign regulatory authorities, such as the 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, as of June 30, 2021, 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, 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 and seek regulatory approval thereof, to complete the clinical development of our intended biologics for use within the RaniPill capsule, to expand our manufacturing capabilities 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 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 the RaniPill capsule 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.

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, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. 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.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates or technologies.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and/or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, current stockholders' interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. The incurrence of indebtedness and/or the issuance of certain equity securities could result in fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur debt and/or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our Class A common stock to decline. In the event that we enter into collaborations and/or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to the RaniPill capsule or our product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

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

We are early in our development efforts and have only one product candidate, RT-101, in early clinical development. All of 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 one product candidate, RT-101, in early clinical development. Our initial goal is to evaluate the safety of the RaniPill capsule, independent of any biologic, through a clinical trial conducted under an IDE. Any delays or setback in the clinical testing of the RaniPill capsule independent of any biologic, which we plan to undertake prior to submitting an IND for any of our candidates, could delay or prevent the clinical testing of any of our current or future product candidates. We completed a Phase 1 clinical trial of RT-101, the RaniPill capsule containing octreotide, in Australia to evaluate safety as a primary endpoint and bioavailability as a secondary endpoint. Our other product candidates are still in the formulation and preclinical stages. We intend to initiate Phase 1 clinical trials for certain of these product candidates in 2022 and in 2023. We will need to progress these product candidates through IND-enabling studies and submit INDs to the FDA 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 New Drug Applications ("NDAs"), from the FDA, and maintaining such approvals;
- establishing clinical and commercial manufacturing capabilities;
- 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 have not yet succeeded and 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.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

Our business and future profitability is substantially dependent on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize the RaniPill capsule with oral versions of multiple biologics. Our approach presents a novel method of delivering biologics directly into the intestinal wall, and we are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or any comparable foreign regulatory authorities. The pathway for obtaining regulatory approval for our approach has not been definitively established, and we may never receive such regulatory approval for any of our product candidates. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. Approval policies, regulations and the types and amount of clinical and manufacturing data necessary to gain approval may change during the course of clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we have in development or may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

- the results of clinical trials may fail to achieve the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data submitted in support of regulatory approval;

- the data collected from preclinical studies and clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other regulatory submissions necessary to obtain regulatory approval in the United States or elsewhere;

- we may not meet the cGMP and other applicable requirements for manufacturing processes, procedures, documentation and facilities necessary for approval by the FDA or comparable foreign regulatory authorities; and

- changes to the approval policies or regulations of the FDA or comparable foreign regulatory authorities with respect to our product candidates may result in our clinical data becoming insufficient for approval.

The lengthy regulatory approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market the RaniPill capsule with our core programs and any other biologics, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain regulatory approval, regulatory authorities may approve our product candidates for fewer or more limited indications than what we requested approval for, may include safety warnings or other restrictions that may negatively impact the commercial viability of our product candidates, including the potential for a favorable price or reimbursement at a level that we would otherwise intend to charge for our products. Likewise, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, which could significantly reduce the potential for commercial success or viability of our product candidates. Any of the foregoing possibilities could materially harm the prospects for our product candidates and business and operations.

We have not previously submitted a BLA, an MAA, or any corresponding drug approval filing to the FDA or any comparable foreign regulatory authorities for any product candidate. Further, our product candidates may not receive regulatory approval even if we complete such filing. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

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. Further, we have never conducted a Phase 2 or Phase 3 clinical trial or submitted an application for marketing authorization.

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 trial of RT-101 do not ensure that future Phase 2 or later clinical trials of RT-101 will have similar results or be successful. In our Phase 1 clinical trial of RT-101, 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 preclinical studies or clinical trial, 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. We have never conducted a Phase 2 or Phase 3 clinical trial or submitted a BLA or comparable marketing application to foreign regulatory authorities, and as a result, we have no history or track-record to rely on when entering these phases of the development cycle. Furthermore, we are currently optimizing the formulation for RT-101, to enable once daily dosing. If we are able to optimize the formulation, we plan to test and verify the formulation in appropriate animal models. Once the formulation is validated in preclinical studies, we plan to submit an IND and initiate clinical trials for the development of RT-101. The scale-up development related to this formulation could delay commencement of such clinical trials, and the revised formulation could cause RT-101 to perform differently than the original formulation and affect the results of our planned clinical trials.

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 ("EC") 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 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 ECs 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 biologic 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 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 only one product candidate, RT-101, in early clinical development. We completed a Phase 1 clinical trial of RT-101 to evaluate safety as a primary endpoint and bioavailability as a secondary endpoint. Our other product candidates are still in the formulation or preclinical stages. We intend to initiate Phase 1 clinical trials for certain of these product candidates in 2022 and in 2023. However, we have not, to date, submitted an IND for any of our product candidates. However, 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 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 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 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 patients 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 biologic 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 and 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 biologic 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.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, or be unable to enroll or maintain, a sufficient number of patients to complete any of our clinical trials. Patient enrollment and retention in clinical trials is a significant factor in the timing of clinical trials and depends on many factors, including the size and nature of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical trial sites and the eligibility criteria for the clinical trial.

For example, we are developing RT-108 for the treatment of hemophilia A, a rare bleeding disorder with limited patient populations from which to draw volunteers in clinical trials. We will be required to identify and enroll a sufficient number of patients with hemophilia A for each of our ongoing and planned clinical trials of RT-108. Potential patients for RT-108 may not be adequately diagnosed or identified with the disease we are targeting or may not meet the entry criteria for our trials. For example, some patients with hemophilia A may seek liver transplants early and as a result become ineligible for our treatment. Additionally, other pharmaceutical companies targeting this same bleeding disorder are recruiting clinical trial patients from these patient populations, which may delay or make it more difficult to fully enroll our clinical trials. For most of our product candidates, we are working to deliver known biologic products via the RaniPill platform, and accordingly, patients who are currently prescribed or eligible to be prescribed the approved injectable versions of these biologics may be unable or unwilling to participate in our clinical trials to test an unapproved delivery system of these medications. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

Furthermore, any negative results we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same candidate. Also, negative results in clinical trials by other companies regarding the biologics we are using or biosimilars or analogs thereof can additionally make it difficult or impossible to recruit and retain patients in our clinical trials. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible.

Our preclinical studies and clinical trials have been affected and may in the future be affected by the COVID-19 pandemic, such as by a reduction in staffing at a CRO, a pause in clinical trial patient enrollment to focus on, and direct resources to, COVID-19, or patients choosing not to enroll or continue participating in a clinical trial as a result of the pandemic. For example, we are developing RT-106 and RT-103 as an oral version of basal insulin and GLP-1 mimetic, respectively, for the treatment of Type 2 diabetes. According to the Centers for Disease Control and Prevention, people who have Type 2 diabetes are at higher risk of getting severely ill from COVID-19. As a result, potential patients in contemplated clinical trials may choose to not enroll, not participate in follow-up clinical visits or drop out of the trial as a precaution against contracting COVID-19 if not vaccinated. Further, some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services.

Our product candidates or similar investigational or approved drugs may cause undesirable side effects or have other properties impacting safety that could delay or prevent the regulatory approval of, limit the commercial profile of an approved label for, or result in limiting the commercial opportunity for our product candidates if approved.

Undesirable side effects that may be caused by our product candidates or caused by similar investigational or approved drugs within the same class by other companies, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or adverse events related to our product candidates. In such an event, our clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of our product candidates for any or all targeted biologic indications.

For example, in our Phase 1 clinical trial of RT-101, the RaniPill capsule was well tolerated by all subjects, and no subjects had difficulty swallowing the pill. Capsule remnants were passed by all trial subjects and no serious adverse events were observed. However, we have generated limited clinical data with the RaniPill capsule to date, and further analysis may reveal adverse events inconsistent with the safety profile observed to date.

Drug-related side effects could negatively affect patient recruitment or the ability of enrolled patients to complete the trial and even if our clinical trials are completed and our product candidate is approved, drug-related side effects could restrict the label or result in potential product liability claims. Any of these occurrences could significantly harm our business, financial condition and prospects.

Moreover, since our product candidates are being developed for indications for which subcutaneous and IV injectable pharmaceuticals have been approved, we expect that our clinical trials would need to show a risk/benefit profile that is competitive with those existing products and product candidates in order to obtain regulatory approval or, if approved, a product label that is favorable for commercialization.

In addition, similar investigational or approved drugs within the same class as our product candidates may encounter serious adverse events. In the event these products encounter serious adverse events, the FDA may remove the class of drugs from the market, impose a class wide REMS, or require other class wide regulatory requirements. We may face increased regulatory scrutiny and ultimately may have to abandon our product candidate of the same class, which would have an adverse effect on our business, financial condition and operations.

Additionally, if one or more of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;

- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate which could significantly harm our business and prospects.

As an organization, we recently completed our first Phase 1 clinical trial, have not submitted an IND to the FDA and we have never conducted later-stage clinical trials or submitted a BLA, 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 is a complicated process. As an organization, we recently completed our first Phase 1 clinical trial for RT-101 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 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. For example, we plan to initiate two clinical trials in 2022. 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, through the pre-submission process with the Center for Devices and Radiological Health (CDRH), and we have never filed an IDE or IND. Although we plan to engage with FDA's Center for Drug Evaluation and Research (CDER) and/or Center for Biologics Evaluation and Research (CBER) to request guidance on our clinical development plan, we have not done so, to date, and 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 for and commercializing our product candidates.

Our product candidates are subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels and the ability to hire and retain key personnel and accept the payment of user fees. In addition, approval policies or regulations may change, and the FDA has substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of our third-party manufacturers with which we contract for clinical and commercial supplies;
- regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed biologics may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new biologics based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from 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, including potentially initiating two clinical trials across our product candidates in 2022, 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 biologic formulations for use in the RaniPill capsule. While we intend to focus on well-characterized molecules with attractive commercial characteristics, focusing both on biologics delivery and formulation will require substantial resource and attention. In addition, we may identify other target payloads that are larger than the current capacity of the RaniPill capsule and we would need to redesign and conduct additional preclinical and clinical studies of any future 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.

A breakthrough therapy designation or Fast Track designation by the FDA for a drug may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that the drug will receive marketing approval.

In the future, we may seek a breakthrough therapy designation for one or more of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the biologics license application.

Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meets the conditions for qualification, or it may decide that the time period for FDA review or approval will not be shortened.

We may seek Fast Track designation for some of our product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address significant unmet medical needs for this condition, the drug sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidates is eligible for this designation, the FDA may not decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. If our clinical development program does not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended, or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation and priority review do not change the standards for approval. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse

differences between preliminary or interim data and final data could significantly harm our business prospects. Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Product candidates comprising a biologic 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. 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 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. We anticipate that our marketing applications to the FDA will have to be submitted as 351(a) BLAs. 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 FDA's CDRH regarding our planned evaluation of the RaniPill platform under an IDE, we have not yet engaged in formal interactions with CDER or CBER to obtain FDA feedback on the clinical trials that will be necessary to support BLA 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.

We have limited clinical data on our product candidates to indicate whether they are safe or effective for long-term use in humans.

We have limited clinical data on our product candidates and we have not conducted any studies to evaluate whether they are safe or effective for long-term use in humans, including to evaluate the safety of any degradation products that may result after the drug is injected into the intestinal wall. In our Phase 1 clinical trial of RT-101, 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 preclinical studies or clinical trial, 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.

If treatment with any of our product candidates in our ongoing or future clinical trials results in concerns about their safety or efficacy, we and our collaboration partners may be unable to successfully develop or commercialize any or all of our product candidates or enter into collaborations with respect to our product candidates.

We have conducted and may in the future conduct clinical trials for current or future product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We have conducted and may in the future choose to conduct one or more clinical trials outside the United States. For example, we conducted a Phase 1 study of RT-101 in Australia. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice regulations ("GCP"); and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data

through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Risks Related to Commercialization of Our Product Candidates

Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates, when and if any of them are approved.

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive requirements imposed by the FDA and comparable foreign regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers, if any, will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA or MAA. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our product candidates will be subject to limitations on the approved indicated uses for which the product may be marketed and promoted or to the conditions of approval (including the requirement to implement a risk evaluation and mitigation strategy), or contain requirements for potentially costly post-marketing testing. We will be required to report certain adverse reactions and production problems, if any, to the FDA and comparable foreign regulatory authorities. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed, and distributed only for the approved indications and in accordance with the provisions of the approved labeling. We will have to comply with requirements concerning advertising and promotion for our products. The holder of an approved BLA or MAA must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling, or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. If original marketing approval was obtained via the accelerated approval pathway, we could be required to conduct a successful post-marketing clinical trial to confirm clinical benefit for our products. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory authorities may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may, among other things:

- issue warning letters that would result in adverse publicity;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approvals;
- suspend any of our ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;

- impose restrictions on our operations, including closing our contract manufacturers' facilities;
- seize or detain products; or
- require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Even if our product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, government payors (including Medicare and Medicaid programs), private insurers, and other third-party payors, or others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, government payors, other third-party payors and other healthcare providers. If any of our approved products fail to achieve an adequate level of acceptance, we may not generate significant revenue to become profitable. The degree of market acceptance, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the potential or perceived advantages or disadvantages of the oral delivery of biologics as compared to subcutaneous or IV injections of biologics;
- the efficacy of our product candidates compared to alternative treatments;
- the shelf-life of our product candidates;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments;
- our ability to offer our product candidates for sale at competitive prices;
- the willingness of the target patient population to try the RaniPill capsule;
- 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;
- the willingness of physicians to prescribe use of the RaniPill capsule and to prescribe biologics that utilize the RaniPill capsule;
- the willingness of the medical community to offer patients our product candidates in addition to or in the place of current subcutaneous and IV injectable therapies;
- the strength of marketing and distribution support;
- the availability of government and third-party coverage and adequate reimbursement;
- our ability to manufacture sufficient supply to meet patients' demand;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product candidates together with other medications or treatments.

Because we expect sales of our product candidates, if approved, to generate revenue for us to achieve profitability, the failure of our product candidates to achieve market acceptance would harm our business and could require us to seek collaborations or undertake additional financings sooner than we would otherwise plan.

The FDA and comparable foreign regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found or alleged to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and comparable foreign regulatory authorities strictly regulate the promotional claims that may be made about prescription products, as our product candidates would be, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or comparable foreign regulatory authorities as reflected in the product's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. If we receive marketing approval for any one of our product candidates, physicians could prescribe such product to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would adversely affect our business and financial condition.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford medications and therapies. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain adequate pricing that will allow us to realize a sufficient return on our investment.

Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new products are typically made by CMS, an agency within the United States Department of Health and Human Services. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel products such as ours since there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries may cause us to price our product candidates on less favorable terms that we currently anticipate. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United

States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

We face significant competition from other biotherapeutics and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotherapeutics and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors worldwide, including major multinational pharmaceutical companies, biotherapeutics companies, specialty pharmaceutical and generic pharmaceutical companies as well as universities and other research institutions.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, and experienced marketing and manufacturing organizations. Mergers and acquisitions in our industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Competition may increase further as a result of advances in the commercial applicability of newer technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, pharmaceutical products that are easier to develop, more effective or less costly than any product candidates that we are currently developing or that we may develop. Unforeseen technological advances to those of our technologies may be developed by these competitors. If approved, our product candidates are expected to face competition from commercially available drugs as well as drugs and devices that are in the development pipelines of our competitors.

Pharmaceutical companies may invest heavily to accelerate discovery and development of novel technologies or to in-license novel technologies that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate advantages in efficacy, convenience, tolerability or safety in order to overcome price competition and to be commercially successful. If our competitors succeed in obtaining FDA or comparable foreign regulatory approval before we do or develop blocking intellectual property to which we do not have a license, there would be a material adverse impact on the future prospects for our product candidates and business.

We face competition primarily from current and future (generic and biosimilars) manufacturers of subcutaneous and IV injectable versions of our product candidates, such as AbbVie Inc., Eli Lilly and Company, Novartis AG, Roche Holdings AG and the SOMA and LUMI from the Novo Nordisk-MIT collaboration. Additionally, we face competition from companies that are pursuing the development and manufacture of oral biologics, including Oramed Pharmaceuticals, Inc., Entera Bio Ltd., Applied Molecular Transport Inc., Protagonist Therapeutics, Inc., Chiasma, Inc., and Novo Nordisk A/S. For example, Chiasma received FDA approval for an oral octreotide product, MYCAPSSA, in June 2020. We also face competition from gene and cell therapy companies. Further, our product candidates aim to treat chronic diseases. As a result, we also compete with curative therapies on the basis that they cure the chronic disease we are intending to treat.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of our product candidates, in particular compared to marketed products and products in late-stage development;
- the time it takes for our product candidates to complete clinical development and receive regulatory approval, if at all;
- the ability to commercialize and market any of our product candidates that receive regulatory approval;
- the price of our products, including in comparison to branded or generic competitors;

- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to protect our intellectual property rights related to our product candidates;
- the ability to avoid infringing on the intellectual property rights of others;
- the ability to manufacture and sell commercial quantities of any of our product candidates that receive regulatory approval; and
- acceptance of any of our product candidates, if approved, by payors, patients, and physicians and other healthcare providers, including perception of the safety and efficacy of the oral delivery of biologics.

Because our research approach depends on our proprietary RaniPill platform, it may be difficult for us to continue to successfully compete in the face of rapid changes in technology. If we fail to continue to advance the RaniPill platform, technological change may impair our ability to compete effectively and technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

We currently have no marketing and sales organization. To the extent any of our product candidates for which we maintain commercial rights is approved for marketing, if we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell any of our product candidates, or generate product revenue.

We currently do not have a marketing or sales organization for the marketing, sales and distribution of biologics products. In order to commercialize any product candidates that receive marketing approval, we would have to build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In the event of successful development of any of our product candidates, we may elect to build a targeted specialty sales force which will be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. With respect to our product candidates, we may choose to partner with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into collaborations with third parties for the commercialization of approved products, if any, on acceptable terms or at all, or if any such partner does not devote sufficient resources to the commercialization of our products or otherwise fails in commercialization efforts, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future revenue will be materially and adversely impacted.

If the market opportunities for any product that we develop are smaller than we believe they are, our commercial revenue may be adversely affected and our business may suffer.

Our projections of both the number of people who have the diseases we may be targeting, as well as the subset of people with these health issues who have the potential to benefit from treatment with our current and any of our future product candidates are based on our beliefs and estimates. For example, we are developing RT-101 for the treatment of acromegaly, for which we estimate the patient population is approximately 25,000 people in the United States as of November 2016, RT-102, an oral administration of parathyroid hormone (PTH) for the treatment of osteoporosis, for which we estimate the patient population is approximately 10.0 million in the United States as of 2018, and RT-105, an oral administration of TNF-alfa antibody for the treatment of psoriatic arthritis, for which we estimate the patient population is approximately 2.4 million in the United States as of March 2014. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new information may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria for indications included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patients, and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Even if we obtain significant market share for our products, if approved, if the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Additional time may be required to obtain regulatory approval for our product candidates because they are combination products.

We believe our product candidates are biologic-device combination products that require coordination within the FDA and comparable foreign regulatory authorities for review of their device and biologic components. Although the FDA and comparable foreign regulatory authorities have systems in place for the review and approval of combination products such as ours, we may experience delays in the development and commercialization of our product candidates due to regulatory timing constraints and uncertainties in the product development and approval process.

Even if we obtain and maintain approval for any of our product candidates from the FDA, we may never obtain approval for our product candidates outside of the United States, which would limit our market opportunities and adversely affect our business.

Sales of our product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval and, to the extent that we retain commercial rights following clinical development, we would plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and additional foreign countries. Even if the FDA grants marketing approval for a product candidate, comparable foreign regulatory authorities must also approve the manufacturing and marketing of that product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to approval. We may decide to submit an MAA to the EMA for approval in the EEA. As with the FDA, obtaining approval of an MAA from the EMA is a similarly lengthy and expensive process and the EMA has its own procedures for approval of product candidates. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Foreign regulatory authorities in countries outside of the United States and the EEA also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by comparable foreign regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any of our product candidates may be withdrawn. If we fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected.

Risks Related to Our Reliance on Third Parties

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

In the past, we have entered into evaluation agreements with Takeda and certain other pharmaceutical companies concerning the formulation and manufacture of oral versions of Factor VIII and other molecules. We currently have no active evaluation agreements. Future evaluation agreements, and any additional collaborations entered into, may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and growth prospects. While we plan to expand our reach by selectively entering into strategic partnerships, we may not be able to enter into such partnerships, and if we do, we may not be able to maintain significant rights or control of future development and commercialization of our product candidates. Accordingly, if we collaborate with a third party for development and commercialization of a product candidate, we may relinquish some or all of the control over the future success of that product candidate to the third party, and that partner may not devote sufficient resources to the formulation and manufacture of our product candidate or may otherwise fail in these efforts, in which event the formulation and manufacture of the product candidate in the collaboration could be delayed or terminated and our business could be substantially harmed.

We believe our product candidates are biologic-device combination products that we anticipate will be regulated under the biologic regulations of the FDA based on its primary mode of action as a biologic. Third-party manufacturers may not be able to comply with the regulatory requirements, known as cGMP, applicable to biologic-device combination products, including applicable provisions of the FDA's drug and biologics cGMP regulations, device cGMP requirements embodied in the medical device Quality System Regulations ("QSRs"), or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product

candidates, operating restrictions and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit any BLA to the FDA.

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

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

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

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

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or do not meet regulatory requirements or expected deadlines, we may not be able to obtain timely regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage clinical trials and collect data during our preclinical studies and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that their conduct meets regulatory requirements and that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. Thus, we and our CROs are required to comply with GCPs, which are regulations and guidelines promulgated by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may not accept the data or may require us to perform additional clinical trials before considering our filing for regulatory approval or approving our marketing application. We cannot assure you that upon inspection by a regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCPs. While we have agreements governing activities of our CROs, we may have limited influence over their actual performance and the qualifications of their personnel conducting work on our behalf. Failure to comply with applicable regulations in the conduct of the clinical studies for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the volunteers participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to

our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We depend on third-party suppliers for key materials used in our manufacturing processes as well as for the manufacturing of biosimilars and the loss of these third parties or their inability to supply us with adequate materials and biosimilars could harm our business.

We rely on third-party suppliers for the supply of the raw materials and APIs required for the production of our product candidates, and we may to some extent rely on third-party manufacturers for the commercial supply of any of our product candidates for which we seek to obtain marketing approval. In addition, we work with third parties to manufacture and develop biologics for inclusion in the RaniPill capsule.

Our dependence on these third parties and the challenges we may face in obtaining adequate supplies of raw materials, APIs and biosimilars involve several risks, including limited control over pricing, availability, quality, delivery schedules and non-exclusivity. As a small company, our negotiation leverage is limited, and we are likely to get lower priority than our competitors who are larger than we are. We do not have long-term supply agreements, and we purchase our required supplies on a development manufacturing services agreement or purchase order basis or the like. These third parties may not continue to provide us with the quantities of these materials that we require to satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials, APIs or biosimilars could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could have an adverse effect on our business, financial condition and results of operations.

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

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

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

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

Risks Related to Our Business and Industry

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing, degree of success and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our product candidates, which may change from time to time;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for any approved products, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of preclinical studies or clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

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 only one product candidate, RT-101, in 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 used to treat multiple diseases and disorders. Our initial goal is to evaluate the safety of the RaniPill capsule independent of any biologic. The RaniPill capsule may not receive regulatory approval in connection with any biologic 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 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 completed a Phase 1 clinical trial of our most advanced product candidate, RT-101, and have completed preclinical studies of other product candidates. We plan to initiate Phase 1 clinical trials of certain product candidates in 2022 and in 2023. 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, and we do not expect to be in a position to do so for the near term.

We have not previously submitted a BLA 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 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.

We may not be successful in our efforts to use and expand our proprietary RaniPill platform to build a pipeline of product candidates.

A key element of our strategy is to leverage the RaniPill platform to expand our pipeline of product candidates and in order to do so, we must continue to invest in the RaniPill platform and development capabilities. Although our research and development efforts to date have resulted in a pipeline of our core product candidates, these product candidates may not be safe and effective and may not obtain regulatory approval. In addition, although we plan to develop the RaniPill platform to deliver a diverse pipeline of product candidates across multiple diseases and disorders, we may not prove to be successful at doing so. Furthermore, we may also find that the uses of the RaniPill platform are limited because alternative uses of our biologics prove not to be safe or effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance. Even after approval, if we cannot successfully develop or commercialize our products, or if serious adverse events are discovered after commercialization, we will not be able to generate any product revenue, which would adversely affect business.

Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ECs for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

The policies of the FDA and comparable foreign regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current or any of our future product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing

approval that we may have obtained, and we may not achieve or sustain profitability, which would harm our business, prospects, financial condition and results of operations.

If we are required to conduct additional clinical trials or other preclinical studies with respect to our current or future product candidates, or if we are unable to successfully complete our preclinical studies or planned clinical trials, we may be delayed in obtaining regulatory approval of our current or any of our future product candidates, we may not be able to obtain regulatory approval at all or we may obtain approval for indications that do not provide a broad commercial opportunity. Our product development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for our current or any of our future product candidates. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business would be harmed.

All of our product candidates, except for RT-101, are in research or preclinical development and have not entered into clinical trials. If we are unable to develop, test and commercialize our product candidates, our business will be adversely affected.

As part of our strategy, we seek to discover, develop and commercialize a portfolio of product candidates that deliver different biologics through the RaniPill capsule. Research programs to identify appropriate biological targets and product candidates require substantial scientific, technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including:

- our financial and internal resources are insufficient;
- our research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates uncompetitive;
- our product candidates may be shown to have harmful side effects or other characteristics that indicate such product candidate is unlikely to be effective or otherwise unlikely to achieve applicable regulatory approval;
- our product candidates may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- our product candidates may not be accepted by patients, the medical community, healthcare providers or third-party payors.

Our proprietary RaniPill platform may not result in any products of commercial value.

We have developed a proprietary platform designed to enable the administration of biologics previously only administrable by subcutaneous or IV injection, and this approach forms the basis of our overall development strategy for all of our product candidates.

For multiple reasons, the RaniPill platform may not ultimately be commercially valuable, including:

- the RaniPill platform may not work in conjunction with our targeted biologic indications or future indications to yield product candidates that can enter clinical development;
- we may not be successful in our efforts to expand the applicability of the RaniPill platform beyond our current product pipeline;
- we may not be able to enter into licensing or partnership agreements on suitable terms to obtain and develop oral versions of biologics; and
- the medical community may not accept the RaniPill platform and physicians may not prescribe our products to patients, if approved.

In addition, we have designed our platform to be drug-agnostic, which we believe could enable us to expand into additional markets beyond our current pipeline. While our research and development efforts support the use of the peptides and antibodies we have evaluated to date for inclusion in the RaniPill capsule, there could be molecules that are unable to be inserted in

the RaniPill capsule, whether as a result of payload capacity, mechanism of action, or otherwise, the result of which would significantly harm our product candidates' commercial potential.

Furthermore, the product candidates contemplated by our current product pipeline were designed with needles that have the ability to deliver 3.0 to 3.5mg of a biologic, which we refer to as payload capacity. We are aware of biologics that require a dose of nearly 100.0mg in order to be effective, such as oncology biologics and certain other cell therapies. While we plan to develop a needle with a payload capacity of up to 30.0mg, which could enable us to expand our platform to include additional molecules, we may still be precluded from using certain high load biologics for inclusion in the RaniPill capsule, which could adversely affect the commercial potential of the RaniPill platform. Additionally, to the extent we are able to develop a needle with a larger payload capacity, we may be required to conduct additional preclinical or clinical studies to establish performance characteristics of the updated design, and for regulatory authorities to permit evaluation of the updated design in human subjects.

As a result of any one of these factors, our business, financial condition and results of operations could be adversely affected.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any of our product candidates, if approved.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to stop development or, if approved, limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- delay or termination of clinical studies;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- decreased demand for our product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue from product sales; and
- the inability to commercialize any our product candidates, if approved.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the development or commercialization of our product candidates. We currently carry $10.0 million in clinical trial liability insurance, which we believe is appropriate for our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

The manufacture and packaging of biologics is subject to FDA requirements and those of comparable foreign regulatory authorities. If we or our third-party manufacturers fail to satisfy these requirements, our product development and commercialization efforts may be harmed.

The manufacture and packaging of biologics is regulated by the FDA and comparable foreign regulatory authorities and must be conducted in accordance with the FDA's cGMP and comparable requirements of foreign regulatory authorities. There are a limited number of manufacturers that operate under these cGMP regulations who are both capable of manufacturing biologics and willing to do so. Failure by us or our third-party manufacturers to comply with applicable regulations or requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product, operating restrictions and criminal prosecutions, any of which could harm our business. Our product candidates require aseptic manufacturing techniques that may present additional manufacturing challenges compared to other oral route of administration products. The same requirements and risks are applicable to the suppliers of the key raw material used to manufacture the active pharmaceutical ingredient ("API"), for the biologics of our product candidates.

Manufacturers of combination products need to comply with both pharmaceutical cGMPs and medical device QSRs enforced by the FDA through its facilities inspection programs. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these cGMP and QSR requirements and with other FDA and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any of our product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize such product candidate, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in the commercialization of our product candidates, entail higher costs or even prevent us from effectively commercializing our product candidates.

Changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, may require prior FDA review and approval of the manufacturing process and procedures in accordance with the FDA's cGMPs and QSRs. Any new facility is subject to a pre-approval inspection by the FDA and would again require us to demonstrate product comparability to the FDA. We would also need to verify, such as through a manufacturing comparability study, that any new manufacturing process would produce our product candidate according to the specifications previously submitted to the FDA, and there are comparable foreign requirements. The delays associated with the verification of a new third party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. This review may be costly and time consuming and could delay or prevent the launch of a product.

Furthermore, in order to obtain approval of our product candidates by the FDA and comparable foreign regulatory authorities, we will be required to consistently produce our formulation of the API, and the finished product in commercial quantities and of specified quality on a repeated basis and document our ability to do so. This requirement is referred to as process validation. Each of our potential API suppliers will likely use a different method to manufacture API, which has the potential to increase the risk to us that our manufacturers will fail to meet applicable regulatory requirements. We also need to complete process validation on the finished product in the packaging we propose for commercial sales. This includes testing of stability, measurement of impurities and testing of other product specifications by validated test methods. If the FDA does not consider the result of the process validation or required testing to be satisfactory, we may not obtain approval to launch the product or approval, launch or commercial supply after launch may be delayed.

The FDA and comparable foreign regulatory authorities may also implement new requirements, or change their interpretation and enforcement of existing requirements, for manufacture, packaging or testing of products at any time. If we are unable to comply, we may be subject to regulatory actions, civil actions or penalties which could harm our business.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or

- indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. On December 2, 2020, the OIG, published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. This rule (with exceptions) became effective January 19, 2021;

- the federal false claims and civil monetary penalties laws, including the False Claims Act, which can be enforced through civil whistleblower or qui tam actions, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims;

- HIPAA, which created new federal criminal statutes that prohibit a person or entity from, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by HITECH, and their implementing regulations, which also imposes obligations, including mandatory contractual terms, on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental program;

- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid

- or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to certain payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the

pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Further, in March 2010, the ACA, among other things, amended the intent requirements of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Moreover, while we do not submit claims and our customers make the ultimate decision on how to submit claims, from time to time, we may provide reimbursement guidance to our customers. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and significant settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we, or our directors, officers, employees, independent contractors, and/or agents, may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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 new 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 new 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. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017 ("Tax Act"), included a provision that decreased the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the "individual mandate," to $0, effective January 1, 2019. On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. The United States Supreme Court is currently reviewing this case, although it is unclear when a decision will be made or how the Supreme Court will rule. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. Further, although the Supreme Court has not yet ruled on the constitutionality of the ACA, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began February 15, 2021 and will remain open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the ACA.

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, will remain in effect through 2030 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 December 31, 2021 due to the COVID-19 pandemic. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years. 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. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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, particularly in light of the new presidential administration, 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.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies, which is time-consuming and costly. If coverage and reimbursement of our product candidates are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate highly qualified personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. Our ability to compete in the highly competitive biotherapeutics and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical, engineering and regulatory personnel. We are highly dependent on our founder and Executive Chairman, Mir Imran, and our existing senior management team, especially Talat Imran, our Chief Executive Officer, Mir Hashim, our Chief Scientific Officer, Svai Sanford, our Chief Financial Officer and Stephanie McGrory, our Vice President of Business Development. We are not aware of any present intention of any of these individuals to leave us. All of our employees may terminate their employment with us at any time, with or without notice. In addition, we manufacture the RaniPill capsule internally. As a result, we rely and will continue to rely on highly qualified manufacturing personnel to manufacture the RaniPill capsule. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements would harm our manufacturing efforts as well as our business, financial condition and prospects. Our success depends on our ability to continue to attract, retain and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management training and skills.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biotherapeutics, biotechnology, pharmaceutical and other businesses. Many of the other biopharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation or more diverse opportunities and better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize product candidates and to grow our business and operations as currently contemplated.

We will need to expand the size of our organization, and we may experience difficulties in managing this growth.

As of June 30, 2021, we had 78 full-time employees. As our development and commercialization plans and strategies develop and we operate as a public company, we expect to need additional managerial, operational, scientific, sales, marketing, development, regulatory, manufacturing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including:

- designing and managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our manufacturing and development efforts effectively;
- improving our managerial, development, operational and financial systems and controls; and
- expanding our facilities.

As our operations expand, we expect that we will need to manage relationships with our partners, suppliers, vendors and other third parties. Our future financial performance and our ability to develop and commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We may not be successful in

accomplishing these tasks in growing our company, and our failure to accomplish any of them could adversely affect our business and operations.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed, and our business will be harmed.

We estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies, clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and comparable foreign regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds used in the manufacture of our product candidates;
- the ability of our suppliers to reliably provide the quantity of materials needed to manufacture and commercialize our products;
- the non-occurrence of adverse events or serious adverse events in preclinical studies or clinical trials of our product candidates;
- the efforts of our collaborators and the success of our own efforts with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing, including scale and automation processes, as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and our business and results of operations may be harmed.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although we may not undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include products and completed operations liability, business personal property and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our employees, independent contractors, principal investigators, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information to the FDA, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations established and enforced by comparable foreign regulatory authorities, or (iv) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and third-parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Our headquarters and certain of our data storage facilities are located near known earthquake fault zones. The occurrence of an earthquake, fire or any other catastrophic event could disrupt our operations or the operations of third parties who provide vital support functions to us, which could have a material adverse effect on our business and financial condition.

We and some of the third-party service providers on which we depend for various support functions, such as data storage, are vulnerable to damage from catastrophic events, such as power loss, natural disasters, terrorism and similar unforeseen events beyond our control. Our corporate headquarters is located in San Jose, which in the past has experienced severe earthquakes and fires.

We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our data storage facilities or financial systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do

not have a disaster recovery and business continuity plan in place. We may incur substantial expenses as a result of the absence or limited nature of our internal or third-party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our development plans and business.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Since March 2020 when foreign and domestic inspections were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections to prioritized basis and may experience delays in their regulatory activities. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections and resumed inspections in China and India in 2021. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Should FDA determine that an inspection is necessary for approval and inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interaction evaluation to be appropriate, the agency has stated that it generally intends to issue a complete response letter. Further, if there is an inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or comparable foreign regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

The COVID-19 pandemic could adversely impact our business including our ongoing and planned preclinical studies and clinical trials.

Since COVID-19 surfaced in Fall 2019, the virus has spread to numerous countries, including the United States, resulting in the World Health Organization characterizing COVID-19 as a pandemic. As a result of the COVID-19 pandemic, we have experienced and may continue to experience delays in our preclinical and planned clinical development activities. The COVID-19 pandemic has and may continue to impact the Company's third-party manufacturers and suppliers, which could disrupt its supply chain or the availability or cost of materials. The effects of the public health directives and the Company's work-from-home policies may negatively impact productivity, disrupt its business, and delay clinical programs and timelines and future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on the Company's ability to conduct business in the ordinary course. These and similar, and perhaps more severe, disruptions in the Company's operations could negatively impact business, results of operations and financial condition, including its ability to obtain financing. The extent to which the COVID-19 pandemic will impact our business will depend on future developments, which are highly uncertain and cannot be predicted, such as the continued geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease and to address its impact, including on financial markets or otherwise. As the COVID-19 pandemic continues, we could experience other disruptions that could severely impact our business, current and planned clinical trials and preclinical studies, including:

- inability of our management to travel in connection with establishing partnerships and collaborations;

- delays in receiving the supplies, materials and services needed to conduct preclinical studies and clinical trials;
- disruption of our access to capital in the global financial markets;
- delays or difficulties in enrolling patients in our planned Phase 1 clinical trials of RT-102, RT-109 (an oral administration of human growth hormone ("hGH") for the treatment of growth hormone deficiency) and our other future clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- limitations in resources, including our employees, that would otherwise be focused on the conduct of our business or our current or planned preclinical studies or clinical trials, including because of sickness, the desire to avoid contact with large groups of people or restrictions on movement or access to our facility as a result of government-imposed “shelter in place” or similar working restrictions;
- interruptions or delays in the operations of the FDA or comparable foreign regulatory authorities, which may impact review and approval timelines;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs or require us to discontinue clinical trials altogether;
- interruptions or delays to our pipeline and research programs; and
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or furlough of government or contractor personnel.

Further, as a result of the COVID-19 pandemic, the extent and length of which is uncertain, we may be required to develop and implement additional clinical trial policies and procedures designed to help protect trial participants from the COVID-19 virus, which may include using telemedicine visits, remote monitoring of patients and clinical sites, and measures to ensure that data from clinical trials that may be disrupted as a result of the pandemic are collected pursuant to the trial protocol and consistent with GCPs, with any material protocol deviation reviewed and approved by the site IRB. Patients who may miss scheduled appointments, any interruption in trial drug supply, or other consequence that may result in incomplete data being generated during a trial as a result of the pandemic must be adequately documented and justified. For example, on March 18, 2020, the FDA issued a guidance on conducting clinical trials during the pandemic, which describe a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report (or as a separate document) contingency measures implemented to manage the trial, and any disruption of the trial as a result of the COVID-19 pandemic; a list of all trial participants affected by the COVID-19-pandemic related trial disruption by unique subject identifier and by investigational site, and a description of how the individual’s participation was altered; and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or trial, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the trial.

Further, the COVID-19 pandemic may impact patient enrollment in our planned future Phase 1 clinical trials. In particular, some sites may delay enrollment to focus on, and direct resources to, COVID-19, while at other sites, patients may choose not to enroll or continue participating in the clinical trial as a result of the pandemic. Potential patients in our planned clinical trials may choose to not enroll, not participate in follow-up clinical visits, or drop out of the trial as a precaution against contracting COVID-19. Further, some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services.

Additionally, three vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020 and early 2021, and more are likely to be authorized in the coming months. The resultant demand for vaccines and potential for

manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our planned clinical trials, which could lead to delays in these trials.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our Class A common stock or such sales may be on unfavorable terms.

While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition, and operating results. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

Our internal computer systems, or those used by our third-party collaborators or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security and back-up measures, our internal computer, server, and other information technology systems as well as those of our third-party collaborators, consultants, contractors, suppliers, and service providers, have and may continue to be vulnerable to damage from physical or electronic break-ins, computer viruses, malware, ransomware, natural disasters, terrorism, war, telecommunication and electrical failure, denial of service, and other cyberattacks or disruptive incidents that could result in unauthorized access to, use or disclosure of, corruption of, or loss of sensitive, and/ or proprietary data, including personal information, including health-related information, and could subject us to significant liabilities and regulatory and enforcement actions, and reputational damage. For example, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in any regulatory approval or clearance efforts and significantly increase our costs to recover or reproduce the data, and subsequently commercialize the product. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. If we or our third-party collaborators, consultants, contractors, suppliers, or service providers were to suffer an attack or breach, for example, that resulted in the unauthorized access to or use or disclosure of personal or health information, we may have to notify consumers, partners, collaborators, government authorities, and the media, and may be subject to investigations, civil penalties, administrative and enforcement actions, and litigation, any of which could harm our business and reputation. Likewise, we rely on our third-party research institution collaborators and other third parties to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. The COVID-19 pandemic has generally increased the risk of cybersecurity intrusions. For example, there has been an increase in phishing and spam emails as well as social engineering attempts from “hackers” hoping to use the recent COVID-19 pandemic to their advantage. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate or unauthorized access to or disclosure or use of confidential, proprietary, or other sensitive, personal, or health information, we could incur liability and suffer reputational harm, and the development and commercialization of the RaniPill capsule could be delayed.

Risks Related to Our Intellectual Property

Our commercial success may depend in part on our ability to build and maintain our intellectual property portfolio.

Our commercial success may depend in part, and perhaps in large part, on having a strong portfolio of intellectual property rights globally to prevent others from copying our products. We rely on a combination of contractual provisions, patent rights, trademark rights, and trade secrets to protect our core technology and products. However, these legal measures may only afford limited protection. For example, we may not be able to obtain or maintain intellectual property rights that we believe are important to our business, or in a form that provides us with a competitive advantage.

Moreover, obtaining and maintaining intellectual property protection is expensive, and reduces the budget available for research, development, and other expenditures. We must balance the need for intellectual property protection against the need for furthering our development and commercialization activities, which may mean that aspects of our technology and methodology may not be protected by our intellectual property portfolio.

Where our intellectual property rights are insufficient to prevent or limit commercialization of competitive products in a jurisdiction, potential competitors might be able to enter or expand in a market more easily, which could have a material adverse effect on our business.

The following ways in which our intellectual property portfolio may be limited represent risks to our capability to reduce competition and thus risks to our business.

We may not be able to obtain sufficient patent coverage.

The process of applying for and obtaining a patent is considerably time consuming and expensive, and we may not have the resources to prepare, file, prosecute, or maintain all desirable patent applications and patents in all jurisdictions where protection may be commercially advantageous. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them, or before others file patent applications covering our product candidates. Moreover, we might not have been the first to make the inventions for which we apply for patents and therefore not be entitled to a patent on such inventions.

Additionally, the scope of our patent coverage may not provide desired coverage for all aspects of our product candidates in all jurisdictions, and scope may differ between jurisdictions. For example, examination of each national or regional patent application is an independent proceeding; as a result, patent applications in the same family may issue with claims of different scope in various jurisdictions, or may even be refused in some or all jurisdictions. If we fail to achieve the desired coverage for all aspects of our product candidates, competitors may be able to copy our technology or design around our patents, and our business may be harmed.

Because the patent position of companies in our industry involves complex legal and factual questions, we cannot predict the validity and enforceability of our patents or provide any assurances that any of our patent applications will be found to be patentable, with certainty. Our issued patents may not provide us with any competitive advantages, may be held invalid or unenforceable as a result of legal challenges by third parties or could be circumvented. Our competitors may also independently develop processes, technologies or products similar to ours or design around or otherwise circumvent any patents issued to, or licensed by, us. Thus, any patents that we own or license from others may not provide adequate protection against competitors. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in patents being issued. If these patents are issued, they may not provide us with proprietary protection or competitive advantages. After the completion of development and registration of our patents, third parties may still manufacture or market our products despite our patent protected rights. If the protection of our proprietary rights is inadequate to prevent use or appropriation by third parties, the value of our brand and other intangible assets may be diminished and competitors may be able to more effectively mimic our technology. If competitors were to mimic our technology, it may result in loss of sales and material litigation expenses. Such infringement of our patent protected rights is likely to cause us damage and lead to a reduction in the prices of our products, thereby reducing our anticipated profits.

We may also inadvertently lose patent assets by failing to follow agency procedures. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent issues. Non-compliance with provisions of the various patent agencies can result in the expiration or abandonment of a patent or patent application, resulting in partial or complete loss of associated patent rights in the relevant jurisdiction.

For example, periodic maintenance fees, renewal fees, and annuity fees must often be paid to the USPTO and various foreign governmental patent agencies over the lifetime of a patent and/or patent application. These maintenance and annuity fees for our patents and patent applications are handled by a third-party annuity provider. Any errors by the annuity provider, including but not limited to, incomplete patent information, missed payment instructions, or errors in fund transfers may cause granted patents to expire and pending patent applications to be deemed abandoned. If we are unable to timely pay the annuity provider for their services, they may cease to pay the maintenance and annuity fees, and our patents and applications may lapse and no longer be in force. Additional non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits and failure to properly legalize and submit formal documents within prescribed time limits. While an unintentional lapse of a patent or patent application can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. This may create opportunities for competitors to enter the market, which could hurt our competitive position and could impair our ability to successfully commercialize our product candidates in any indication for which they are approved. For these and other reasons, we cannot guarantee that our patents will provide a basis for an exclusive market for our commercially viable products, or will even provide us with any competitive advantage.

It is possible that defects of form in the preparation, filing or prosecution of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope or requests for patent term adjustments. If we fail to establish, maintain or protect such patent rights, they may be reduced or eliminated. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, such patents may be invalid and/or

unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We may not be able to obtain sufficient brand protection.

We may rely on a combination of trademarks, service marks, brand names, trade names, and trade dress, and in some cases pending applications for the same, to protect our brands, in an effort to distinguish our products from the products of our competitors. Some of these mechanisms are protectable under state, federal, and foreign trademark laws and regulations. Although limited protection is available without registration, it is preferable to register trademarks in jurisdictions where we may commercialize.

We have registered or applied to register several trademarks in the United States and many other jurisdictions globally. We cannot ensure that our pending trademark applications will be approved. During trademark registration proceedings, our applications may be rejected by the USPTO or foreign agencies, or may be opposed by third parties. Although we are given an opportunity to respond, we may be unable to overcome such rejections or oppositions. In addition, third parties may seek to cancel registered trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are finally rejected or successfully challenged, we could be forced to rebrand, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing with new branding.

Our existing trademarks, whether registered or unregistered, face additional hurdles which may have a material adverse effect on our business. For example: one or more of our current or future trademarks may become used by the public in a manner that the use of the trademark becomes generic and loses its trademark protection in one or more jurisdictions; competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion; and, if we are unable to establish name recognition based on our branding, then we may not be able to compete effectively. Any of the foregoing could have a material adverse effect on our competitiveness.

In addition, our competitors may infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks.

Domain names are also important to our brand identity and commercialization efforts and we have many registered domain names. However, there are several dozens of top-level domains and more coming, and there are several trademarks or other names that we may wish to incorporate into domain names. The combination of domains and names that may be of interest to our business could number in the hundreds or the thousands. Further, many domain names of interest are already registered by a third party. Therefore, we will not be able to obtain each and every domain name that may be of interest to our business. There is a risk that a competitor or other third party could register a domain name that inhibits our ability to advertise, confuses our customers, or redirects our potential business to other companies.

Trademarks and domain names are intended, and in some cases required, to be used by their owners. In the absence of meaningful use, we may be forced to forfeit various ones of our trademarks and domain names.

Intellectual property law and regulation could affect the value of our intellectual property portfolio.

Interpretation of existing laws and regulations is uncertain and may depend on specific facts of a case. Therefore, we cannot be certain of the effectiveness of our intellectual property against third parties. Further, laws and regulations in general may not provide sufficient protection to prevent, or provide adequate remedy for, the infringement, use, violation or misappropriation of our patents, trademarks, data, technology and other intellectual property and services.

Moreover, changes in laws, or changes in interpretations of laws, may unpredictably weaken our ability to obtain, defend, or enforce our intellectual property rights. A weakened ability to obtain, defend, or enforce rights covering our proprietary technologies could materially and adversely affect our business prospects and financial condition. For example, the United States Supreme Court and the United States Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce patents that we own or that we might obtain or license in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. Changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them, or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad.

We cannot predict interpretations of existing laws and regulations, future changes to laws or regulations, or changes in the interpretation of laws or regulations. Such changes could increase uncertainty with respect to the value of patents and trademarks once obtained.

Intellectual property rights do not provide complete protection for our business activities.

The combination of contractual provisions, confidentiality procedures, and intellectual property rights that we rely on to protect the proprietary aspects of our products, brands, technologies and data afford limited protection. The degree of protection is uncertain, and our intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage.

We may not be able to successfully commercialize our products prior to patent expiration.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or soon after such candidates are commercialized. The exclusivity period provided by a patent is limited; in the United States, if all maintenance fees are timely paid, the expiration of a patent is generally 20 years from its earliest claimed U.S. non-provisional filing date. Even if patents covering our future products are obtained, once the patent life has expired, we may be open to competition from competitive products entering the market and we may suffer a subsequent decline in market share and profits. Although there may be a possibility to extend the term of one or more of our patents through various laws and regulations, most of our patents will not be eligible for such term extension. An example of legislation providing patent term extension is the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in some foreign jurisdictions, which provides a patent term extension of up to five years for patent term lost during product development and the FDA regulatory review process.

Our intellectual property rights may not be effective against certain competitive products.

While we seek to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our intellectual property position in various jurisdictions may be inadequate in posing an effective challenge to competitive products, and also may not be conducive to successfully commercializing our product candidates in such jurisdictions.

Further, it is quite possible that a competitor may duplicate portions of our technology, or may develop a similar or alternative technology, without infringing our intellectual property rights; or a competitor may offer similar, duplicative, or competitive products for sale in major commercial markets not covered by our intellectual property rights.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired. In addition, some countries limit the enforceability of patents against government agencies or government contractors.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act which could allow the government, in specified circumstances, to require a company to grant a license to a third party. We do not currently have intellectual property falling under these provisions. We cannot be sure that if we acquire intellectual property in the future it will be free from government rights or regulations pursuant to the Bayh-Dole Act. If, in the future, we own, co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

Third parties may hold intellectual property rights that cover our product candidates.

Our intellectual property rights, including our patent rights, do not give us the right to practice our patented inventions. Third parties may have blocking patents that could prevent us from marketing our own products and practicing our own technology. In some cases, it may be advantageous to license or acquire such patents. However, we may be unable to do so on commercially

reasonable terms, such as on terms that would allow us to make an appropriate return on our investment. In addition, companies that perceive us to be a competitor may be unwilling to transfer or license rights to us. Moreover, the licensing or acquisition of third-party intellectual property rights is a competitive area, and other companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider important to our business. Some such companies may have a competitive advantage over us due to their size, capital resources, clinical development stage, or commercialization capabilities.

If we are unable to successfully obtain or maintain rights to third-party intellectual property rights which we deem important to an aspect of our business, we may deem it to be in our best interests to forego further development of the relevant program or product candidate, which could have a material adverse effect on our business.

We are presently reliant upon an in-license with ICL to certain of ICL's patent rights. Additional in-licenses with other third parties may be negotiated in the future. License agreements may impose fee, royalty, insurance, milestone, and other obligations on us. If we fail to comply with our obligations to a licensor, that licensor may have the right to terminate our license, in which event we might not be able to develop, manufacture or market any product that is covered by the intellectual property we in-license. Such an occurrence would materially adversely affect our business prospects.

Further, we are presently party to a service agreement, which is defined below, with ICL. Pursuant to the service agreement, we may engage ICL to perform development work on behalf of our company. We will wholly own intellectual property resulting from such development work only if it relates to the oral delivery of a biotherapeutic agent or sensor, or the Rani Field, and was developed on our time and with our resources. All other resulting intellectual property will be wholly owned by ICL. ICL has agreed to exclusively license certain intellectual property to us for use solely within the Rani Field, but we may not obtain a license on favorable terms.

In addition, intellectual property rights that we in-license in the future may be sublicenses under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our sublicense agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, or if we fail to comply with our development obligations under our license agreements when applicable, our ability to develop and commercialize our product candidates may be materially harmed.

If we do not control the prosecution, maintenance and enforcement of our in-licensed intellectual property, we will not be certain that the prosecution, maintenance and enforcement of the licensed intellectual property rights will be in a manner consistent with the best interests of our business.

Competitors could purchase our products and attempt to replicate or reverse engineer some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, or design around our patents, any of which could materially affect our business, and we may not be able to prevent or stop such actions from occurring.

Legal or administrative proceedings related to intellectual property could materially adversely affect our ability to commercialize our products and could result in significant expenditures of resources.

There are several types of legal or administrative proceedings in which we may become involved, such as the ones outlined below. Any proceeding, even those asserted against us without merit and even those where we prevail, may cause us to incur substantial costs, could place a significant strain on our financial resources, divert the attention of management from our core business, divert our employees from development activities, delay commercialization activities, and harm our reputation.

Others may challenge our intellectual property in administrative proceedings.

Administrative proceedings available for challenging issued patents include re-examination, post grant review, inter partes review, and similar proceedings in foreign jurisdictions as applicable. Such a proceeding could result in a patent being deemed invalid, or the scope of the patent coverage being reduced. Similarly, a registered trademark may be challenged, which could result in loss of the trademark, or reduction in the scope of the trademark. Patents and trademarks that we in-license may also be deemed invalid, or the scope reduced. Any of the foregoing outcomes could affect our ability to commercialize our products.

Our patents are presently being challenged in Europe.

The EPO provides for an opposition proceeding that could result in revocation of or amendment to a patent. We are presently involved in several opposition proceedings at the EPO, all of which were asserted against us by Novo Nordisk AS.

There is a risk that one or more of our issued European patents will be invalidated, 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 invalidated or have its claims amended. Invalidation or amendment could have a material adverse impact on our ability to commercialize in Europe and/or a material adverse impact on our ability to deter competition from potential competitors in Europe.

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

We may assert challenges against others of infringement of our intellectual property.

We may determine that our competitors are infringing our patents or trademarks. In such case we could initiate infringement proceedings against them. Such proceedings are generally quite expensive in terms of money and employee time, and may be prohibitively expensive so that we may decide it not to be cost effective. Indeed, there can be no assurance that we will have sufficient financial or other resources to file and pursue all such proceedings. The monetary costs of such proceedings, the fact that they could last for years before they are concluded, and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. We may also be hindered or prevented from enforcing our rights with respect to a government entity or instrumentality because of the doctrine of sovereign immunity.

Additionally, a legal proceeding might harm our business relationships, and thus we may determine that it is in our best interests not to pursue such course. Moreover, any claims we assert against perceived infringers or other third parties could provoke those parties to assert counterclaims against us alleging, for example, that we infringe their patents or other proprietary rights, that our patents or other proprietary rights are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of any patent is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making or selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are unenforceable, that the alleged infringing mark does not infringe our trademark rights or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this last instance, we could ultimately be forced to cease use of such trademarks. Any of these outcomes could adversely affect our competitive business position, financial condition and results of operations.

Even if our patents or other intellectual property are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market and, thus, may not be commercially meaningful. However, we may not prevail in any legal challenge that we do initiate. Additionally, if a defendant were to prevail on invalidity of our asserted patents, we may lose some, and perhaps all, of the intellectual property protection on our product candidates, which could have a material adverse impact on our business.

Furthermore, because of the substantial amount of discovery that may be required in connection with intellectual property litigation, there is a risk that some of our proprietary information could be compromised by disclosure during litigation.

There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments; if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our stock.

We may be subject to challenges asserting infringement of intellectual property of a third party.

Our commercial success depends, in part, upon our ability to develop, manufacture, market and sell our products and use our proprietary technologies without infringing the intellectual property rights of third parties.

However, despite our efforts to avoid infringement, we may face infringement challenges by competitors, or from non-practicing entities which purchase intellectual property assets for the purpose of making assertions of infringement to extract settlements. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. Even if we believe an infringement challenge to be without merit, a court could find infringement, which could have a negative impact on the commercial success of our current and future products. We do not know the nature of claims contained in unpublished patent applications around the world and it is not possible to know which countries patent applicants may choose for the extension of their filings under the Patent Cooperation Treaty. Accordingly, third parties may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our product candidates. Additionally, our

products include components that we purchase from vendors, and may include components that are outside of our direct control. Vendors from whom we purchase components may not indemnify us if our products incorporating their components are accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secret.

If we are found to infringe a third party's intellectual property rights, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed. In addition, we could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. In some cases, we could pursue a license to continue developing, manufacturing and commercializing our products and technology. However, we may not be able to obtain a license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments.

Further, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. If third parties assert infringement challenges against our customers, these challenges may require us to initiate or defend litigation on behalf of our customers. If any of these challenges succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

The cost to us of any infringement challenge, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of an infringement challenge more effectively because of their greater financial resources. In addition to absorbing significant financial resources, an infringement challenge may also consume management's time. Consequently, there is no assurance that we will be able to develop or commercialize a product candidate in line with our business objectives in the event of an infringement challenge.

Further, the outcome of any infringement challenge is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in patent infringement cases that may turn on the testimony of experts as to technical facts upon which the experts may reasonably disagree.

We may be subject to challenges asserting misappropriation of intellectual property of a third party.

We employ or contract with individuals who were previously employed elsewhere, including at other biopharmaceutical companies such as our competitors or potential competitors. Some of these employees, consultants or contractors may have executed proprietary rights, non-disclosure, or non-competition agreements in connection with such previous employment or contracting. In addition, we use proprietary information and materials from third parties which may be subject to agreements that include restrictions on use or disclosure. Although we strive to ensure proper safeguards, we cannot guarantee strict compliance with such agreements, nor can we be sure that our employees, consultants and advisors do not use proprietary information, materials, or know-how of others in their work for us.

We may be subject to challenges that we or our employees, consultants, or contractors have inadvertently or otherwise used or disclosed proprietary information of our employees' former employers or other third parties. There is no guarantee of success in defending such challenges, and if we are not successful, we may be blocked from using the technology that is the subject of the misappropriation challenge.

We may be subject to challenges to the inventorship or ownership of our intellectual property.

We may in the future be subject to challenges by our former employees or consultants asserting an ownership right in our intellectual property, as a result of the work they performed on our behalf. Although we generally require all of our employees and consultants and any other partners or collaborators who have access to our proprietary know-how, information or technology to assign or grant rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. If we fail in defending any such challenges, we may lose valuable intellectual property rights, including the loss of exclusive ownership of, or right to use, such intellectual property.

Additionally, we may be subject to a challenge from a third party challenging our ownership interest in intellectual property we regard as our own, based on assertions that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any such a challenge. It may be necessary or we may desire to enter into a license to settle any such challenge; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to a challenge fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products,

if such technologies or features are found to incorporate or be derived from the proprietary information of the former employer. An inability to incorporate technologies or features that are important or essential to our products may prevent us from selling our products.

Third parties may obtain our proprietary information, which could harm our business and competitive position.

If any of our proprietary information, including trade secrets and know-how, were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us and our competitive position would be harmed.

We seek to maintain the confidentiality of our proprietary information, relying heavily on confidentiality provisions that we have in agreements with our employees, consultants, collaborators and others upon the commencement of their relationship with us. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our proprietary technology and processes and cannot guarantee that such agreements will not be breached. Moreover, these agreements can be difficult and costly to enforce or may not provide adequate remedies. We also seek to preserve the integrity and confidentiality of our data and other proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these security measures and systems, agreements or security measures may be breached.

Detecting the disclosure or misappropriation of proprietary information and enforcing an assertion that a party illegally disclosed or misappropriated proprietary information is difficult, expensive and time-consuming, the outcome is unpredictable, there may not be an adequate remedy for breach, and many foreign countries do not have laws adequate to protect proprietary rights.

The theft or unauthorized use or publication of our proprietary information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced, and if a third party's proprietary information is disclosed we may face litigation by such third party. Any of the foregoing could materially and adversely affect our business and financial condition.

Risks Related to Our Organizational Structure

We are a holding company and our principal asset is our interest in Rani. Accordingly, we will depend on distributions from Rani to pay our taxes, expenses (including payments under the Tax Receivable Agreement) and dividends. Rani's ability to make such distributions may be subject to various limitations and restrictions.

We are a holding company and have no material assets other than our ownership of LLC Interests of Rani. As such, we have no independent means of generating net sales or cash flow, and our ability to pay our taxes and operating expenses or declare and pay dividends in the future, if any, is dependent upon the financial results and cash flows of Rani and its subsidiary and distributions we receive from Rani. Rani and its subsidiary may not generate sufficient cash flow to distribute funds to us and applicable state law and contractual restrictions, including negative covenants in our debt instruments, may not permit such distributions.

We anticipate that Rani will continue to be treated as a partnership for U.S. federal income tax purposes and, as such, generally will not be subject to any entity-level U.S. federal income tax. Instead, taxable income will be allocated to holders of LLC Interests. Accordingly, we will incur income taxes on our allocable share of any net taxable income of Rani and will also incur expenses related to our operations, including payments under the Tax Receivable Agreement, which we expect could be significant. Furthermore, our allocable share of Rani's net taxable income will increase over time as the Continuing LLC Owners redeem or exchange their LLC Interests for shares of our Class A common stock.

We intend, as its managing member, to cause Rani to make cash distributions to the owners of LLC Interests, including us, in an amount sufficient to (i) fund their or our tax obligations in respect of allocations of taxable income from Rani and (ii) cover our operating expenses, including payments under the Tax Receivable Agreement. However, Rani's ability to make such distributions may be subject to various limitations and restrictions, such as restrictions on distributions that would either violate any contract or agreement to which Rani is then a party, including debt agreements, or any applicable law, or that would have the effect of rendering Rani insolvent. In addition, for taxable years beginning after December 31, 2017, liability for adjustments to a partnership's tax return can be imposed on the partnership itself in certain circumstances, absent an election to the contrary. Rani could be subject to material liabilities pursuant to adjustments to its partnership tax returns if, for example, its calculations or allocations of taxable income or loss are incorrect, which also could limit its ability to make distributions to us.

If we do not have sufficient funds to pay taxes or other liabilities or to fund our operations, we may have to borrow funds, which could adversely affect our liquidity and financial condition and subject us to various restrictions imposed by any such lenders. To the extent that we are unable to make payments under the Tax Receivable Agreement for any reason, such payments generally will

be deferred and will accrue interest until paid; provided, however, that nonpayment for a specified period may constitute a material breach of a material obligation under the Tax Receivable Agreement and therefore accelerate payments due under the Tax Receivable Agreement. In addition, if Rani does not have sufficient funds to make distributions, our ability to declare and pay cash dividends will also be restricted or impaired.

Rani may make distributions of cash to us substantially in excess of the amounts we use to make distributions to our stockholders and pay our expenses (including our taxes and payments under the Tax Receivable Agreement). To the extent we do not distribute such excess cash as dividends on our Class A common stock, the Continuing LLC Owners would benefit from any value attributable to such cash as a result of their ownership of Class A common stock upon an exchange or redemption of their LLC Interests.

We will receive a portion of any distributions made by Rani. Any cash received from such distributions will first be used by us to satisfy any tax liability and then to make any payments required under the Tax Receivable Agreement. Subject to having available cash and subject to limitations imposed by applicable law and contractual restrictions (including pursuant to our debt instruments), the Rani Agreement requires Rani to make certain distributions to us and the Continuing LLC Owners, pro rata, to facilitate the payment of taxes with respect to the income of Rani that is allocated to us and them. These distributions are based on an assumed tax rate, and to the extent the distributions we receive exceed the amounts we actually require to pay taxes, Tax Receivable Agreement payments, and other expenses, we will not be required to distribute such excess cash. Our board of directors may, in its sole discretion, choose to use such excess cash for any purpose, including (i) to make distributions to the holders of our Class A common stock, (ii) to acquire additional newly issued LLC Interests, and/or (iii) to repurchase outstanding shares of our Class A common stock. Unless and until our board of directors chooses, in its sole discretion, to declare a distribution, we will have no obligation to distribute such cash (or other available cash other than any declared dividend) to our stockholders.

No adjustments to the redemption or exchange ratio of LLC Interests for shares of our Class A common stock will be made as a result of either (i) any cash distribution by us or (ii) any cash that we retain and do not distribute to our stockholders. To the extent we do not distribute such cash as dividends on our Class A common stock and instead, for example, hold such cash balances, buy additional LLC Interests or lend them to Rani, this may result in shares of our Class A common stock increasing in value relative to the LLC Interests. The holders of LLC Interests may benefit from any value attributable to such cash balances if they acquire shares of Class A common stock in redemption of or exchange for their LLC Interests or if we acquire additional LLC Interests (whether from Rani or from holders of LLC Interests) at a price based on the market price of our Class A common stock at the time.

The Tax Receivable Agreement with certain of the Continuing LLC Owners requires us to make cash payments to them in respect of certain benefits to which we may become entitled. In certain circumstances, payments under the Tax Receivable Agreement may be accelerated and/or significantly exceed the actual tax benefits we realize.

We are a party to the Tax Receivable Agreement with certain of the Continuing LLC Owners. Under the Tax Receivable Agreement, we will be required to make cash payments to certain of the Continuing LLC Owners equal to 85% of the tax benefits, if any, that we are deemed to realize (calculated using certain assumptions) as a result of (i) increases in the tax basis of assets of Rani resulting from (a) any future redemptions or exchanges of LLC Interests and (b) payments under the Tax Receivable Agreement and (ii) certain other tax benefits arising from payments under the Tax Receivable Agreement. While the actual amount and timing of any payments under the Tax Receivable Agreement, will vary depending upon a number of factors, including the timing of exchanges, the price of shares of our Class A common stock at the time of the redemption or exchange, the extent to which such redemptions or exchanges are taxable, future tax rates, and the amount and timing of our taxable income (prior to taking into account the tax depreciation or amortization deductions arising from the basis adjustments), we expect that, as a result of the size of the increases in the tax basis of the tangible and intangible assets of Rani attributable to our interests in Rani, during the expected term of the Tax Receivable Agreement, the payments that we may make to certain of the Continuing LLC Owners could be significant. See the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Source of Liquidity” for further information.

Payments under the Tax Receivable Agreement will be based on the tax reporting positions that we determine, and the Internal Revenue Service (the “IRS”), or another tax authority may challenge all or part of the tax basis increases, as well as other related tax positions we take, and a court could sustain such challenge. The Continuing LLC Owners who are parties to the Tax Receivable Agreement will not reimburse us for any payments previously made under the Tax Receivable Agreement if such basis increases or other benefits are subsequently disallowed, except that any excess payments made by us to the Continuing LLC Owners under the Tax Receivable Agreement will be netted against future payments that we might otherwise be required to make to the Continuing LLC Owners under the Tax Receivable Agreement. However, a challenge to any tax benefits initially claimed by us may not arise for a number of years following the initial time of such payment or, even if challenged early, such excess cash payment may be greater than the amount of future cash payments that we might otherwise be required to make under the terms of the Tax Receivable Agreement and, as a result, there might not be sufficient future cash payments against which the prior payments can be fully netted. The applicable U.S. federal income tax rules are complex and factual in nature, and there can be no assurance that the IRS

or a court will not disagree with our tax reporting positions. Therefore, payments could be made under the Tax Receivable Agreement in excess of the tax savings that we realize in respect of the tax attributes with respect to the Continuing LLC Owners that are the subject of the Tax Receivable Agreement.

In addition, the Tax Receivable Agreement provides that, upon certain mergers, asset sales or other forms of business combination or certain other changes of control our (or our successor's) obligations with respect to tax benefits would be based on certain assumptions, including that we (or our successor) would have sufficient taxable income to utilize the benefits arising from the increased tax deductions and tax basis and other benefits covered by the Tax Receivable Agreement. Consequently, it is possible, in these circumstances, that the actual cash tax savings realized by us may be significantly less than the corresponding Tax Receivable Agreement payments. Our accelerated payment obligations and/or assumptions adopted under the Tax Receivable Agreement in the case of a change of control may impair our ability to consummate a change of control transaction or negatively impact the value received by owners of our Class A common stock in a change of control transaction.

If we were deemed to be an investment company under the 1940 Act as a result of our ownership of Rani, applicable restrictions could make it impractical for us to continue our business as contemplated and could adversely affect our business, results of operations and financial condition.

Under Sections 3(a)(1)(A) and (C) of the 1940 Act, a company generally will be deemed to be an "investment company" for purposes of the 1940 Act if (i) it is, or holds itself out as being, engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities or (ii) it engages, or proposes to engage, in the business of investing, reinvesting, owning, holding or trading in securities and it owns or proposes to acquire investment securities having a value exceeding 40% of the value of its total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis. We do not believe that we are an "investment company," as such term is defined in either of those sections of the 1940 Act.

As the sole managing member of Rani, we will control and operate Rani. On that basis, we believe that our interest in Rani is not an "investment security" as that term is used in the 1940 Act. However, if we were to cease participation in the management of Rani, our interest in Rani could be deemed an "investment security" for purposes of the 1940 Act.

We and Rani intend to conduct our operations so that we will not be deemed an investment company. However, if we were to be deemed an investment company, restrictions imposed by the 1940 Act, including limitations on our capital structure and our ability to transact with affiliates, could make it impractical for us to continue our business as contemplated and could adversely affect our business, results of operations and financial condition.

ICL currently performs or supports many of our general and administrative corporate functions and will continue to do in the near future pursuant to a service agreement, and if we are unable to replicate or replace these functions if the service agreement is terminated, our operations could be adversely affected.

ICL currently performs or supports a few of the general and administrative corporate functions for our company. For example, ICL provides certain general management, intellectual property, office and information technology services. Our consolidated financial statements reflect charges for these services pursuant to our service agreement with ICL, or the service agreement, which is being renewed on an annual basis. Pursuant to the service agreement, ICL will provide us certain administrative and development support services. For example, we anticipate receiving from ICL certain general management, intellectual property, office and information technology services. In addition, pursuant to the service agreement, we will continue to sublease from ICL office and laboratory space encompassing approximately 23,000 square feet.

Pursuant to the service agreement, we will wholly own intellectual property resulting from ICL's development work only if it relates to the Rani Field and was developed by our team and using our resources. ICL has agreed to exclusively license certain intellectual property to us for use solely within the Rani Field, but we may not obtain a license on favorable terms.

The fees to be charged for any service rendered pursuant to the service agreement will be based upon the hours incurred by ICL employees working on behalf of Rani as well as allocations of expenses based upon Rani's utilization of ICL's facilities and equipment for the relevant period.

The service agreement will renew for successive one-year terms unless sooner terminated by either party. Termination of individual services requires 60 days' notice, and termination of the service agreement requires six months' notice. In the event the service agreement is terminated by us or ICL, we will need to replicate or replace certain functions, systems and infrastructure to which we will no longer have the same access. We may also need to make investments or hire additional employees to operate without the same access to ICL's existing operational and administrative infrastructure. These initiatives may be costly to implement. Due to the scope and complexity of the underlying projects relative to these efforts, the amount of total costs could be materially higher than our estimate, and the timing of the incurrence of these costs is subject to change.

In addition, we may not be able to replace these services or enter into appropriate third-party agreements on terms and conditions, including cost, comparable to those that we will receive from ICL under the service agreement. When we begin to operate these functions separately, if we do not have our own adequate systems and business functions in place, or are unable to obtain them from other providers, we may not be able to operate our business effectively or at comparable costs, and our profitability may decline.

Rani is controlled by certain of the Continuing LLC Owners, whose interests may differ from those of our public stockholders.

Certain of the Continuing LLC Owners control approximately 94% of the combined voting power of our common stock through their ownership of both Class A common stock and Class B common stock. These Continuing LLC Owners will, for the foreseeable future, have the ability to substantially influence us through their ownership position over corporate management and affairs, and will be able to control virtually all matters requiring stockholder approval. These Continuing LLC Owners are able to, subject to applicable law, elect a majority of the members of our board of directors and control actions to be taken by us and our board of directors, including amendments to our certificate of incorporation and bylaws and approval of significant corporate transactions, including mergers and sales of substantially all of our assets. The directors so elected will have the authority, subject to the terms of our indebtedness and applicable rules and regulations, to issue additional stock, implement stock repurchase programs, declare dividends and make other decisions. It is possible that the interests of these Continuing LLC Owners may in some circumstances conflict with our interests and the interests of our other stockholders, including you. For example, these Continuing LLC Owners may have different tax positions from us, especially in light of the Tax Receivable Agreement, that could influence our decisions regarding whether and when to dispose of assets, whether and when to incur new or refinance existing indebtedness, and whether and when Rani should terminate the Tax Receivable Agreement and accelerate its obligations thereunder. In addition, the determination of future tax reporting positions and the structuring of future transactions may take into consideration these Continuing LLC Owners' tax or other considerations, which may differ from the considerations of us or our other stockholders.

The multi-class structure of our common stock may adversely affect the trading price or liquidity of our Class A common stock.

The existence of three classes of our common stock could result in less liquidity for any such class than if there were only one class of our capital stock. In addition, S&P Dow Jones and FTSE Russell have announced changes to their eligibility criteria for inclusion of shares of public companies on certain indices that will exclude companies with multiple classes of shares of common stock from being added to such indices. Several stockholder advisory firms also have announced their opposition to the use of multiple class structures. As a result, the multi-class structure of our common stock may prevent the inclusion of our Class A common stock in such indices and may cause stockholder advisory firms to publish negative commentary about our corporate governance practices or otherwise seek to cause us to change our capital structure. Any such exclusion from indices could result in a less active trading market for our Class A common stock. Any actions or publications by stockholder advisory firms critical of our corporate governance practices or capital structure could also adversely affect the value of our Class A common stock.

The multi-class structure of our common stock has the effect of concentrating voting control which will limit your ability to influence the outcome of important transactions, including a change in control.

Our Class B common stock has 10 votes per share, our Class A common stock has one vote per share and Class C common stock has no voting rights, except as required by law. Holders of our outstanding Class A common stock collectively hold approximately 6% of the voting power of our outstanding capital stock, holders of our outstanding Class B common stock collectively hold approximately 94% of the voting power of our outstanding capital stock. Because of the 10-to-one voting ratio between our Class B common stock and Class A common stock, the holders of our Class B common stock collectively control a majority of the combined voting power of our capital stock and therefore are able to control all matters submitted to our stockholders for approval so long as the shares of our Class B common stock represent at least 9.1% of all outstanding shares of our Class A common stock and Class B common stock. These holders of our Class B common stock may also have interests that differ from other stockholders and may vote in a way which may be adverse to other stockholder interests. This concentrated control may have the effect of delaying, preventing or deterring a change in control of our company, could deprive our stockholders of an opportunity to receive a premium for their capital stock as part of a sale of our company and might ultimately affect the market price of our Class A common stock.

The exchange of Class A units for Class A common stock will have the effect, over time, of increasing the relative voting power of those holders of Class B common stock who retain their shares in the long term. If, for example, Mir Imran, together with his affiliates, retains a significant portion of his holdings of our Class B common stock for an extended period of time, he could control a significant portion of the voting power of our capital stock for the foreseeable future. As a board member, Mir Imran owes a fiduciary duty to our stockholders and must act in good faith and in a manner to be in the best interests of our stockholders. As a stockholder, Mir Imran is entitled to vote his shares in his own interests, which may not always be in the interests of our stockholders generally.

Risks Related to Our Class A Common Stock

We do not know whether an active, liquid and orderly trading market will develop for our common stock.

We only recently completed our IPO, so there is limited history regarding the trading of our Class A common stock. An active trading market for our Class A common stock may not develop or be sustained. The lack of an active market may impair stockholders' ability to sell their shares at the time or price they wish to sell them. In addition, as described further in these "Risk Factors," a substantial percentage of our Class A common stock will continue to be held by our executive officers and pre-IPO investors, who will be subject to lock-up agreements expiring 180 days from July 30, 2021, subject to standard exemptions. As a result of these and other factors, stockholders may be unable to resell their shares of our Class A common stock at or above the initial public offering price. Further, an inactive market may also impair our ability to raise capital by selling shares of our Class A common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of Class A common stock as consideration.

Our stock price may be volatile and the value of our Class A common stock may decline.

The market price of our Class A common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report on Form 10-Q, these factors including:

- our ability to obtain and maintain regulatory approvals for our current or any of our future product candidates;
- changes in laws or regulations applicable to our current or any of our future product candidates;
- adverse developments concerning any of our third-party collaborators and suppliers;
- our inability to obtain adequate product supply for our current or any of our future product candidates or our inability to do so at acceptable prices; 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;
- the degree and rate of physician and market adoption of our current or any of our future product candidates;
- announcements by us or our competitors of significant business developments, diagnostic technologies, acquisitions, or new offerings;
- negative publicity associated with issues related to our technology or our product candidates;
- our inability to establish collaborations, if needed;
- future sales of our Class A common stock or other securities, by us or our stockholders, as well as the anticipation of lock-up releases;
- changes in senior management or key personnel;
- the trading volume of our Class A common stock;
- performance or news releases by other companies in our industry including about adverse developments related to safety, effectiveness, accuracy and usability of their products, reputational concerns, reimbursement coverage, regulatory compliance, and product recalls;
- general economic, regulatory and market conditions, including economic recessions or slowdowns;
- changes in the structure of healthcare payment systems;
- actual or anticipated fluctuations in our financial condition and results of operations, including as a result of anticipated or unanticipated demand based on seasonal factors;

- variance in our financial performance from expectations of securities analysts or investors;
- changes in our projected operating and financial results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions, including the COVID-19 pandemic; and
- other events or factors, many of which are beyond our control.

Broad market and industry fluctuations, as well as general economic, pandemic, political, regulatory, and market conditions, may negatively impact the market price of our Class A common stock. In addition, given the relatively small public float of shares of our Class A common stock on Nasdaq, the trading market for our shares may be subject to increased volatility. In the past, securities class action litigation has often been brought against companies that have experienced volatility or following a decline in the market price of its securities. This risk is especially relevant for us, because medical device companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We are a "controlled company" within the meaning of the Nasdaq rules and, as a result, qualify for, and may rely on, exemptions and relief from certain corporate governance requirements. If we rely on these exemptions, our stockholders will not have the same protections afforded to stockholders of companies that are subject to such requirements.

Following our IPO, our executive Chairman, Mir Imran beneficially owns approximately 80% of the combined voting power of our Class A and Class B common stock. As a result, we will continue to be a "controlled company" within the meaning of the Nasdaq corporate governance standards. Under these corporate governance standards, a company of which more than 50% of the voting power in the election of directors is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements. For example, controlled companies are not required to have:

- a board that is composed of a majority of "independent directors," as defined under the Nasdaq rules;
- a compensation committee that is composed entirely of independent directors; and
- director nominations be made, or recommended to the full board of directors, by its independent directors, or by a nominations/governance committee that is composed entirely of independent directors.

While we do not intend to rely on the exemptions relating to being a "controlled company" within the meaning of the Nasdaq rules, we may utilize these exemptions for as long as we continue to qualify as a "controlled company." Accordingly, our stockholders may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of the Nasdaq. Investors may find our Class A common stock less attractive as a result of our reliance on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

We may in the future engage in acquisitions, collaborations, or strategic partnerships, which may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may engage in various acquisitions, collaborations, and strategic partnerships in the future, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any acquisition, collaboration, or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- volatility with respect to the financial reporting related to such arrangements;
- assumption of indebtedness or contingent liabilities;
- issuance of our equity securities which would result in dilution to our stockholders;

- assimilation of operations, intellectual property, products, and product candidates of an acquired company, including difficulties associated with integrating new personnel;

- diversion of our management's attention from our existing product programs and initiatives in pursuing such an acquisition or strategic partnership;

- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and

- our inability to generate revenue from acquired intellectual property, technology, and/or products sufficient to meet our objectives or even to offset the associated transaction and maintenance costs.

In addition, if we undertake such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense.

Future sales and issuances of our Class A common stock in the public market could cause the market price of our Class A common stock to decline.

Sales and issuances of a substantial number of shares of our Class A common stock in the public market, or the perception that these sales might occur, could depress the market price of our Class A common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales and issuances may have on the prevailing market price of our Class A common stock.

As of September 10, 2021, we have 19,714,592 outstanding shares of Class A common stock. Of these shares, only 7,666,667 shares of Class A common stock are freely tradable.

In addition, all of our executive officers and directors and the holders of substantially all of our equity securities are subject to lock-up agreements that restrict their ability to transfer shares of our Class A common stock, stock options and other securities convertible into, exchangeable for, or exercisable for our Class A common stock during the period ending on, and including, the 180th day after July 30, 2021, subject to specified exceptions. BofA Securities, Inc. and Stifel, Nicolaus & Company, Incorporated may, in their discretion, permit our stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements. Upon the expiration of the lock-up period, all of such shares will be eligible for sale.

We intend to register all of the shares of Class A common stock issuable upon exercise of outstanding stock options, and upon exercise or settlement of any options or other equity incentives we may grant in the future, for public resale under the Securities Act. Accordingly, these shares will be able to be freely sold in the public market upon issuance as permitted by any applicable vesting requirements, subject to the lock-up agreements described above. These shares of common will become eligible for sale in the public market to the extent such stock options are exercised, subject to the lock-up agreements described above and compliance with applicable securities laws.

Continuing LLC Owners are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our Class A common stock.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval and may prevent other stockholders from influencing significant corporate decisions.

As of September 10, 2021, our named executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially hold approximately 64% of our outstanding stock, representing approximately 83% of our voting power. Therefore, these stockholders have substantial influence and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of voting power could, among other things, delay or prevent an acquisition of our company on terms that other stockholders may desire, which in turn could depress our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

These stockholders, acting together, will be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

We do not intend to pay dividends for the foreseeable future and, as a result, your ability to achieve a return on your investment will depend on appreciation in the price of our Class A common stock.

We have never declared or paid any cash dividends on our capital stock, and we do not intend to pay any cash dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and may be restricted by the terms of any then-current debt instruments. Accordingly, stockholders must rely on sales of their Class A common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of the Nasdaq require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel devotes a substantial amount of time to ensure that we comply with all of these requirements, and we will likely need to hire additional accounting and financial staff with appropriate public company reporting experience and technical accounting knowledge. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to continue to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq and other applicable securities rules and regulations impose various requirements on public companies. Furthermore, the senior members of our management team do not have significant experience with operating a public company. As a result, our management and other personnel need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs. Accordingly, we expect to continue to incur operating losses for the foreseeable future and we may not achieve profitability in the future and that, if we do become profitable, we may not sustain profitability. Our failure to achieve and sustain profitability in the future will make it more difficult to finance our business and accomplish our strategic objectives, which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our Class A common stock to decline.

Provisions under Delaware law and California law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Under our amended and restated certificate of incorporation, we have elected not to be governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any holder of at least 15% of our capital stock for a period of three years following the date on which the stockholder acquired at least 15% of our common stock. Because our principal executive offices are located in California, the anti-takeover provisions of the California Corporations Code may apply to us under certain circumstances now or in the future.

We are an emerging growth company and a smaller reporting company and our compliance with the reduced reporting and disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our Class A common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we expect to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including the auditor attestation requirements of Section 404 reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote

on executive compensation and stockholder approval of any golden parachute payments not previously approved and extended adoption period for accounting pronouncements.

We are also a "smaller reporting company," as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Investors may find our Class A common stock less attractive as a result of our reliance on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our Class A common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a requirement that special meetings of stockholders be called only by holders of at least 25% of the voting power of our Class A common stock and Class B common stock, voting together as a single class, the chairperson of the board of directors, the chief executive officer, or by a majority of the board of directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of a majority of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation, with protective provisions in our certificate of incorporation requiring approval of a majority of the voting power of the Class B common stock then outstanding;
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of Class A common stock; and
- the authorization of three classes of common stock as described above.

Under our amended and restated certificate of incorporation, we have elected not to be governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business antitakeover provisions. Other provisions in our amended and restated certificate of incorporation and amended and restated bylaws, could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our Class A common stock to decline.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (1) any

derivative action or proceeding brought on our behalf, (2) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders, (3) any action or proceeding asserting a claim against us or any of our current or former directors, officers, or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, (4) any action or proceeding to interpret, apply, enforce, or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws, (5) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware, and (6) any action asserting a claim against us or any of our directors, officers, or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants.

These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation and our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and the provisions may not be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the exclusive forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

As a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting, and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our Class A common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the year ending December 31, 2022, which is the year covered by the second annual report following the completion of our initial public offering. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting in our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company if we are not a non-accelerated filer at such time.

If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our Class A common stock could decline, and we could be subject to sanctions or investigations by the SEC or comparable foreign regulatory authorities. Failure to remedy any material weakness or significant deficiency in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our Class A common stock.

The preparation of our financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. If our assumptions underlying our estimates and judgments relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgments, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our Class A common stock.

Unanticipated changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could adversely affect our results of operations and financial condition

We are or may be subject to taxes by the U.S. federal, state, local and foreign tax authorities, and our tax liabilities will be affected by the allocation of expenses to differing jurisdictions. Our future effective tax rates could be subject to volatility or adversely affected by a number of factors, including:

- changes in the valuation of our deferred tax assets and liabilities;
- expected timing and amount of the release of any tax valuation allowances;
- tax effects of equity-based compensation;
- changes in tax laws, regulations or interpretations thereof; or
- future earnings being lower than anticipated in countries where we have lower statutory tax rates and higher than anticipated earnings in countries where we have higher statutory tax rates.

In addition, we may be subject to audits of our income, sales and other transaction taxes by U.S. federal, state, local and foreign taxing authorities. Outcomes from these audits could adversely affect our business, results of operations and financial condition.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our Class A common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our Class A common stock. Such a delisting would likely have a negative effect on the price of our Class A common stock and would impair a stockholder's ability to sell or purchase our Class A common stock when they wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our Class A common stock to become listed again, stabilize the market price or improve the liquidity of our Class A common stock, prevent our Class A common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the FCPA the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct or may in the future conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other third-party collaborators from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties outside of the United States to sell our products internationally once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our

employees, agents, contractors and other third-party collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

We are subject to numerous laws and regulations related to anti-bribery and anti-corruption laws, such as the FCPA, in which violations of these laws could result in substantial penalties and prosecution.

For any operations outside the United States, we are similarly subject to various heavily-enforced anti-bribery and anti-corruption laws, such as the FCPA and similar laws around the world. These laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third-party business partners and intermediaries, fail to comply with the FCPA or other anti-corruption and anti-bribery laws. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, our internal control policies and procedures and employee training and compliance programs designed to deter prohibited practices ultimately may not be effective in preventing our employees, contractors, business partners, intermediaries or agents from violating or circumventing our policies and/or the law.

Responding to any enforcement action or related investigation may result in a significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA or other applicable anti-bribery, anti-corruption or anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could harm our business, financial condition and results of operations.

If securities or industry analysts do not publish research or publish unfavorable or inaccurate research about our business, our Class A common stock price and trading volume could decline.

Our stock price and trading volume will be heavily influenced by the way analysts and investors interpret our financial information and other disclosures. If securities or industry analysts do not publish research or reports about our business, delay publishing reports about our business or publish negative reports about our business, regardless of accuracy, our Class A common stock price and trading volume could decline.

The trading market for our Class A common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We expect that only a limited number of analysts will cover our company. If the number of analysts that cover us declines, demand for our Class A common stock could decrease and our Class A common stock price and trading volume may decline. Even if our Class A common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over-reliance by analysts or investors on any particular metric to forecast our future results may result in forecasts that differ significantly from our own.

Regardless of accuracy, unfavorable interpretations of our financial information and other public disclosures could have a negative impact on our stock price. If our financial performance fails to meet analyst estimates, for any of the reasons discussed above or otherwise, or one or more of the analysts who cover us downgrade our Class A common stock or change their opinion of our Class A common stock, our stock price would likely decline.

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

During the three months ended June 30, 2021, we issued and sold the following unregistered securities:

(a) On April 19, 2021, we issued 1,000 shares of common stock at a purchase price of $0.01 per share for aggregate gross proceeds of $10.00 to Rani.

(b) On June 17, 2021, Rani granted certain of its employees, consultants, directors and executive officers options to purchase 2,292,309 common units with an exercise price of $4.99 per share.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise specified above, we believe these transactions were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and

appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Use of Proceeds from Registered Securities

On July 29, 2021, the SEC declared effective our Registration Statement on Form S-1 (File No. 333-257809), as amended, filed in connection with our IPO. In connection with the IPO, we issued and sold 7,666,667 shares of our Class A common stock, which included 1,000,000 shares sold pursuant to the full exercise by the underwriters of their option to purchase additional shares, at the initial public offering price to the public of $11.00 per share. The initial closing of the IPO occurred on August 3, 2021. The closing of the underwriters' partial exercise of 500,000 shares of our Class A common stock occurred on August 11, 2021, and the closing of the underwriters' exercise of their remaining option of 500,000 shares of our Class A common stock occurred on August 13, 2021. We received aggregate gross proceeds from the IPO of approximately $84.3 million, before deducting underwriting discounts and commissions of approximately $5.9 million and other expenses of approximately $4.7 million. BofA Securities, Inc., Stifel, Nicolaus & Company, Incorporated, Cantor Fitzgerald & Co. and Canaccord Genuity LLC acted as joint book-running managers for the offering. BTIG LLC acted as lead manager for the offering.

None of the expenses associated with the IPO were paid or are payable, directly or indirectly, to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates.

There has been no material change in the planned use of proceeds from our IPO as described in the Prospectus.

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 9, 2021).
3.2	Amended and Restated Bylaws of the Registrant as currently in effect (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 9, 2021).
4.1	Specimen Class A common stock certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 26, 2021).
10.1	Tax Receivable Agreement, effective as of August 3, 2021 (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 16, 2021).
10.2	Class B Unit Exchange Agreement, effective as of August 3, 2021 (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 16, 2021).
10.3	Registration Rights Agreement, effective as of August 3, 2021 (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 16, 2021).
10.4	Fifth Amended and Restated Limited Liability Company Agreement of Rani Therapeutics, LLC, effective as of August 3, 2021 (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 16, 2021).
10.5+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, filed with the SEC on July 9, 2021).
10.6+	Rani Therapeutics Holdings, Inc. 2021 Equity Incentive Plan and forms of agreement thereunder (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 26, 2021).
10.7+	Rani Therapeutics Holdings, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 26, 2021).
10.8+	Rani Therapeutics Holdings, Inc. Severance and Change in Control Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, filed with the SEC on July 9, 2021).
10.9+	Form of Participation Agreement under the Rani Therapeutics Holdings, Inc. Severance and Change in Control Plan (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1, filed with the SEC on July 9, 2021).
10.10+	Rani Therapeutics Holdings, Inc. Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, as amended, filed with the SEC on July 16, 2021).
10.11	Amended and Restated Exclusive License Agreement, by and between Rani Therapeutics, LLC and InCube Labs, LLC, dated June 22, 2021 (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1, filed with the SEC on July 9, 2021).
10.12	Non-Exclusive License Agreement, by and between Rani Therapeutics, LLC and InCube Labs, LLC, dated June 22, 2021 (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1, filed with the SEC on July 9, 2021).
10.13	Intellectual Property Agreement, by and between Rani Therapeutics, LLC and Mir A. Imran, dated June 22, 2021 (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1, filed with the SEC on July 9, 2021).
10.14+	Amended and Restated Employment Agreement, dated June 17, 2021, by and between Rani Management Services, Inc. and Talat Imran (incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1, filed with the SEC on July 9, 2021).
10.15+	Amended and Restated Employment Agreement, dated June 17, 2021, by and between Rani Management Services, Inc. and Mir Hashim (incorporated by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-1, filed with the SEC on July 26, 2021).
10.16+	Amended and Restated Employment Agreement, dated June 17, 2021, by and between Rani Management Services, Inc. and Svai Sanford (incorporated by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1, filed with the SEC on July 9, 2021).
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)

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* 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 Company 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 Form 10-Q), irrespective of any general incorporation language contained in such filing.

+ Indicates management contract or compensatory plan.

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: September 13, 2021 By: /s/ Talat Imran

Talat Imran
Chief Executive Officer
(Principal Executive Officer)

Date: September 13, 2021 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: September 13, 2021

/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: September 13, 2021

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

Exhibit 32.1

CERTIFICATION

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

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2021, 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: September 13, 2021

In Witness Whereof, the undersigned have set their hands hereto as of the 13th day of September, 2021.

/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."